

Generics Pharma Basics

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Disclaimer

It is safe to assume that I am personally invested in any stock ideas that might be referred to in the presentation. My views will be biased. This is NOT a stock recommendation. Kindly do your own due diligence and/or consult a registered investment advisor before making any investment decisions.

ANDA – abbreviated new drug application

- Formulations – consumed directly by patients
- Number of competing molecules mainly determines the margins
- Each company should file ANDA for getting approval for selling
- We get good idea by finding out number of competing ANDAs
- Orange book – orange book on US FDA site has whole ANDA database along with listed patent
- (see reference slide for links)

Example 1: Methoxasalen

- Small market: 13.5 M USD. Limited competition: higher margin Co: strides acrolab

Overview

Drug Name	METHOXSALEN
Active Ingredient(s)	• METHOXSALEN
Form(s) and Strength(s) Available	• CAPSULE;ORAL: 10MG

Details about drugs are organized by FDA Application Number (NDA or ANDA or BLA).

Click on a drug name or application number to view drug details:

Click on a column header to re-sort the table:

Drug Name and FDA Application Number	Label Info	Dosage Form/Route	Strength	Marketing Status	Company
METHOXSALEN (ANDA # 087781)	Not Available	CAPSULE;ORAL	10MG	Discontinued	SANDOZ
METHOXSALEN (ANDA # 202603)	Not Available	CAPSULE;ORAL	10MG	Prescription	ACTAVIS INC
METHOXSALEN (ANDA # 202687)	Not Available	CAPSULE;ORAL	10MG	Prescription	STRIDES PHARMA

Example 2: ibuprofen

- Link <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>
- Ex; ibuprofen EQ200MG has 4 ANDAs – one marksans pharma (likely softgel)
- Ibuprofen as such has more than 30 ANDAs – will be low margin

IBUPROFEN (ANDA # 077338)	Not Available	CAPSULE;ORAL	EQ 200MG FREE ACID AND POTASSIUM SALT	Over-the-counter	P AND L DEV LLC
IBUPROFEN (ANDA # 077349)	Not Available	TABLET;ORAL	200MG	Over-the-counter	PERRIGO R AND D
IBUPROFEN (ANDA # 078132)	Not Available	TABLET;ORAL	Multiple Strengths	Discontinued	NORTHSTAR HLTHCARE
IBUPROFEN (ANDA # 078329)	Not Available	TABLET;ORAL	Multiple Strengths	Prescription	SHASUN USA
IBUPROFEN (ANDA # 078558)	Not Available	TABLET;ORAL	Multiple Strengths	Prescription	AMNEAL PHARMS NY
IBUPROFEN (ANDA # 078682)	Not Available	CAPSULE;ORAL	EQ 200MG FREE ACID AND POTASSIUM SALT	Over-the-counter	BANNER LIFE SCIENCES
IBUPROFEN (ANDA # 079058)	Not Available	SUSPENSION/DROPS;ORAL	40MG/ML	Over-the-counter	TRIS PHARMA INC
IBUPROFEN (ANDA # 079129)	Not Available	TABLET;ORAL	200MG	Over-the-counter	SVADS HOLDINGS SA
IBUPROFEN (ANDA # 079174)	Not Available	TABLET;ORAL	200MG	Over-the-counter	GRANULES INDIA
IBUPROFEN (ANDA # 079205)	Not Available	CAPSULE;ORAL	EQ 200MG FREE ACID AND POTASSIUM SALT	Over-the-counter	MARKSANS PHARMA
IBUPROFEN (ANDA # 079233)	Not Available	TABLET;ORAL	200MG	Over-the-counter	AMNEAL PHARMS
IBUPROFEN (ANDA # 090796)	Not Available	TABLET;ORAL	Multiple Strengths	Prescription	MARKSANS PHARMA
IBUPROFEN (ANDA # 091237)	Not Available	TABLET;ORAL	200MG	Over-the-counter	MARKSANS PHARMA
IBUPROFEN (ANDA # 091239)	Not Available	TABLET;ORAL	200MG	Over-the-counter	MARKSANS PHARMA
IBUPROFEN (ANDA # 091355)	Not Available	TABLET;ORAL	200MG	Over-the-counter	SVADS HOLDINGS SA
IBUPROFEN (ANDA # 200457)	Not Available	SUSPENSION;ORAL	100MG/5ML	Over-the-counter	AMNEAL PHARMS
IBUPROFEN (ANDA # 202300)	Not Available	CAPSULE;ORAL	EQ 200MG FREE ACID AND POTASSIUM SALT	Over-the-counter	AMNEAL PHARMS

Exclusivity

- Any product will have two kinds of protection
 - patent
 - exclusivity by US FDA
- Patent will be for 10 years
- Innovators will make lot of profits
- Hence US FDA came up with exclusivity clause as paragraph IV

Para IV explained

A new application for a innovator molecule (ANDA) should have listed patents – these are covered in orange book

Hatch Waxman act – when a generic launches it should file ANDA with

- a) Para III – FDA approves after last patent expires
- b) Para IV– generic does not infringe patent or patents from innovator are invalid

On receipt of para iv – innovator has 45 days to file patent infringement suite. Once filed, FDA cannot authorize generic for 30 months or file closed in court
If a generic company is first to file, it gets first 180 day exclusivity – leading to significant profits

See reference slide for example of how to see exclusivity expiration

DMF pipeline – for API registrations

- API – Active Pharma Ingredient – basic drug itself with the desired medicinal (pharmaceutical) properties - filed in drug master file (DMF)
- A Formulation is usually composed of two things: The API, which is the drug itself; and an excipient, which is the substance of the tablet, or the liquid the API is suspended in, with other masking, stabilising and binding agents/material
- ANDA filer should give from whom he is buying the API from in his ANDA (but not known publicly)
- <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/UCM370722.xls>
- Filter by your company or API name

What to look for in DMF

- Number of competitors
- **Patent on molecule by API producer will help generic company(developer of formulation) to protect himself against litigations – important for shilpa medicare**
- Patent for api means API holder has found a unique novel way of producing API
- How to search for patents (in reference section)

Other points

- ANDAs filed are not seen on FDA site until they are approved
- If a company does both API and formulations– see the DMF list – we get some idea for which ANDA company MAY file in future (companies do the DMF filing first)
- Example: Alembic , Shilpa (when it files ANDA and gets approval)
- Ajanta, Marksans don't do API

Case study 1 for ANDA: Abilify (aripiprazole)

- Brand name: Abilify API: Aripiprazole
- Innovator: Otsuka
- Exclusivity expiration: 28-april-2015
- Sales : \$7b
- Six filers: Teva, alembic, torrent, hetero, sun, zyclus
- Sun and zyclus did not get approval because of 483s (with plant under 483, you don't get ANDA approvals)
- So finally four got approval: Teva, alembic, hetero, torrent

Abilify (continued)

- Companies were ready before approval. Zauba shows shipments starting from March 31.

31-Mar-2015	30049099	ARIPIRAZOLE TABS 30MG, 30TABS - NDL NO:13811-684-30	United States	Bombay Air Cargo	NOS	10,974	1,109,032	101
31-Mar-2015	30049099	ARIPIRAZOLE TABS 20MG, 100TABS - NDL NO:13811 683 10	United States	Bombay Air Cargo	NOS	708	144,418	204

Ads by Google  [▶ Export Data](#) [▶ Import Companies](#) [▶ Export to China](#) [▶ Meat Export](#)

<< 1 2 3 4 5 >>

Filter by

- Almost 2100 Cr shipped till date from Mumbai
- Hetero from Hyderabad and very less shipment (don't know reason)
- All shipment from Mumbai means most likely Torrent or Alembic (but hetero may also ship)

Abilify – (continued)

- No current market share information available
- FY15 Generic sales for alembic: 518cr
- FY15 Generic sales for Torrent: 832cr
- Total export as seen zauba : 2100cr (one molecule can cause significant impact)
- Does shipments shown in zauba account for price fall ? Don't know
- How many years worth molecules are exported ? Don't know
- Kotak report suggests only 20% price drop – not sure
- IMS will show actual data

Market share information not available to retail investors

- This is from strides investor presentation
 - Successfully launched 5 new products in the US - Calcitriol , Buspirone, Tacrolimus , Imiquimod Cream and Methoxsalen
 - Vancomycin market share increased significantly to 53%
- But FDA site shows 14 competitors. How strides acrolab got 53% market share ?
- Strides does not do direct marketing for this product. Done by avlogen.
- Market share information available in IMS

References & links

How to see number of ANDAs for a molecule

- Orange book – orange book on US FDA site has whole ANDA database along with listed patent
- <http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm>
- Search orange book
- <http://www.accessdata.fda.gov/scripts/cder/ob/docs/queryai.cfm>

How to see exclusivity expiration date

Step1: search orange book

<http://www.accessdata.fda.gov/scripts/cder/ob/docs/queryai.cfm>

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations
FDA Home Drug Databases Orange Book

Start Over

No matching records found. Please enter new search criteria.

Search by Active Ingredient:

(Type in part or all of name)

Select the list you would like to search:

Rx (Prescription Drug Products)
 OTC (Over-the-Counter Drug Products)
 Disc (Discontinued Drug Products)

Step2: Click on application number

Displaying records 1 to 3 of 3 [Download data](#)

Appl No	TE Code	RLD	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
N021446		No	PREGABALIN	CAPSULE; ORAL	100MG	LYRICA	PF PRISM CV
N021446		No	PREGABALIN	CAPSULE; ORAL	150MG	LYRICA	PF PRISM CV
N021446		No	PREGABALIN	CAPSULE; ORAL	200MG	LYRICA	PF PRISM CV

How to see exclusivity expiration date

Step 3: click on the link patent and exclusivity info for this product



Active Ingredient:	PREGABALIN
Dosage Form;Route:	CAPSULE;ORAL
Proprietary Name:	LYRICA
Applicant:	PF PRISM CV
Strength:	25MG
Application Number:	N021446
Product Number:	001
Approval Date:	Dec 30, 2004
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	
Patent and Exclusivity Info for this product:	View

Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
N021446	001	6001876	Dec 30, 2018			U - 55	Y
N021446	001	6001876	Dec 30, 2018			U - 819	Y
N021446	001	6197819	Dec 30, 2018	Y	Y		
N021446	001	RE41920	Dec 30, 2018			U - 1250	

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
N021446	001	I - 651	Jun 20, 2015

How to see market size of drug

- Google 😊
- Look at IMS sales figure in the press release of the MNC company/listed indian company

There are several types of bipolar disorder. Bipolar I disorder is a specific type of bipolar disorder characterized by manic or mixed episodes of feelings of extreme irritability or euphoria. Bipolar I disorder is the most severe form of the illness marked by extreme manic episodes.

Abilify[®] (aripiprazole) Tablets, marketed by Otsuka Pharmaceutical, had annual sales of approximately \$7.8 billion in the United States, according to IMS data as of December 2014.

How to track shipments

- Use zauba.com to track shipments – see some days before exclusivity expiration

aripiprazole Export ▾ Submit

[united states \[X\]](#)

Detailed Export Data of aripiprazole to united states

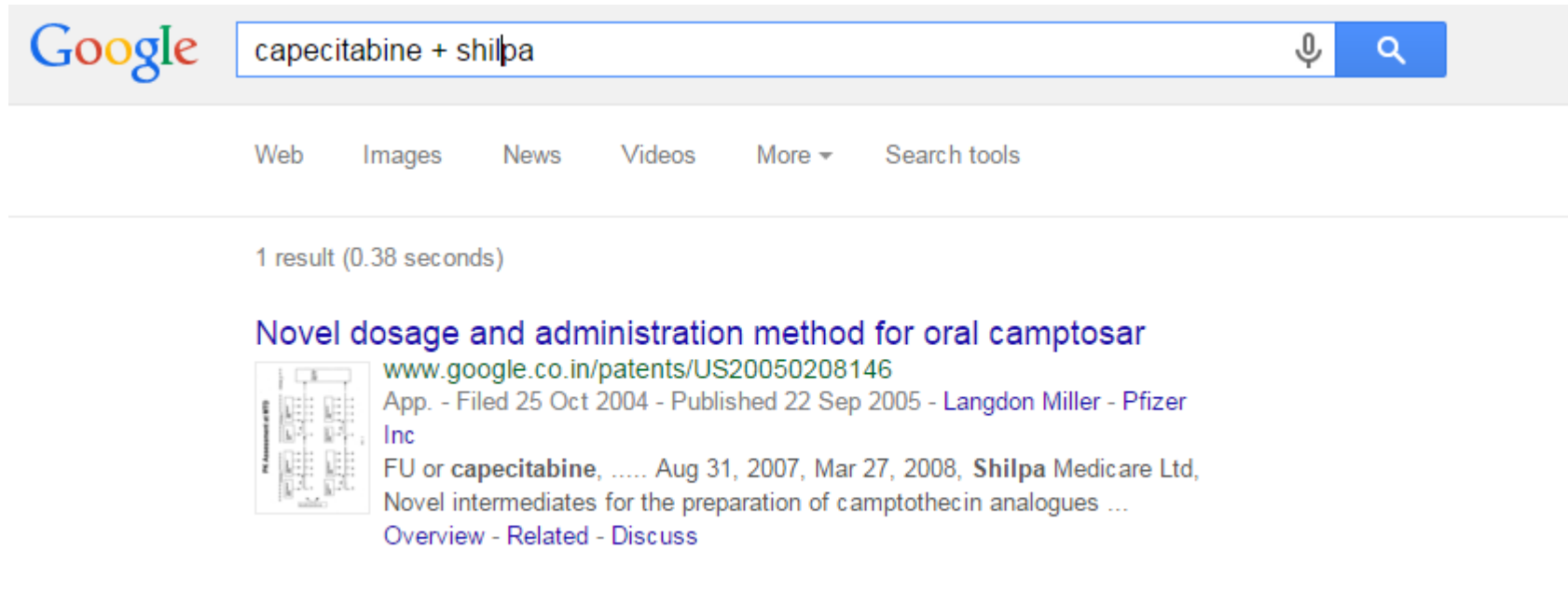
128 export shipment records found.
[Click here to view detailed analysis and trends of Export of aripiprazole](#)

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Date	HS Code	Description	Destination	Port of Loading	Unit	Quantity	Value (INR)	Per Unit (INR)
4-Jun-2015	29334900	ARIPIPRAZOLE USP - BULK DRUG	United States	Bombay Air Cargo	KGS	3	276,545	92,490
2-Jun-2015	29225090	ARIPIPRAZOLE	United States	Hyderabad Air Cargo	KGS	4	335,529	83,882
1-Jun-2015	30049099	ARIPIPRAZOLE TABLETS 5MG (ARIPIPRAZOLE 5MG) - 1x90 TABS	United States	Bombay Air Cargo	PAC	2,568	43,033,300	16,758
1-Jun-2015	30049099	PHARMA : ARIPIPRAZOLE TABLETS 5MG (ARIPIPRAZOLE 5MG) - 1x30 TABS	United States	Bombay Air Cargo	PAC	61,272	342,242,464	5,586
29-May-2015	30049099	PHARMA : ARIPIPRAZOLE TABLETS 10MG (ARIPIPRAZOLE 10MG) - 1x90 TABS	United States	Bombay Air Cargo	PAC	5,088	85,490,656	16,802
29-May-2015	30049099	PHARMA : ARIPIPRAZOLE TABLETS 10MG (ARIPIPRAZOLE 10MG) - 1x30 TABS	United States	Bombay Air Cargo	PAC	36,480	203,932,304	5,590
29-May-2015	30049099	PHARMA : ARIPIPRAZOLE TABLETS 10MG (ARIPIPRAZOLE 10MG) - 1x30 TABS	United States	Bombay Air Cargo	PAC	20,664	115,515,600	5,590

How to search for patents

- Patents.google.com



The screenshot shows a Google search interface. The search bar contains the text "capecitabine + shilpa". Below the search bar, there are navigation links for "Web", "Images", "News", "Videos", "More", and "Search tools". The search results section shows "1 result (0.38 seconds)". The first result is titled "Novel dosage and administration method for oral camptosar" and includes a thumbnail image of a patent document. The text of the result provides the patent number, filing and publication dates, the inventor, and the assignee.

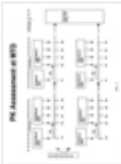
Google

capecitabine + shilpa

Web Images News Videos More Search tools

1 result (0.38 seconds)

Novel dosage and administration method for oral camptosar

 www.google.co.in/patents/US20050208146
App. - Filed 25 Oct 2004 - Published 22 Sep 2005 - Langdon Miller - Pfizer Inc
FU or capecitabine, Aug 31, 2007, Mar 27, 2008, Shilpa Medicare Ltd,
Novel intermediates for the preparation of camptothecin analogues ...
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