Natco Pharma Ltd.

US filings review

Natco Pharma (NATCO) is ~ INR 2000 Crore revenue Pharmaceutical company with exposure to the US generics (40%, FY19) and India Formulations (37%) segments. The company followed a differentiated strategy compared to other generic pharma players for both the US & Indian markets and has been successful in executing it. It pursued litigation driven – specific product opportunities in the US. For the Indian market, it remained focused on time-specific opportunities (like Hep-C) coupled with narrower therapy (Oncology) approach vs broadly diversified model of other companies. It has had a phase of strong profit growth especially over FY16-18 on the back of a low base & successful monetisation of opportunities. FY19 saw some decline, FY20E would most likely see earnings depression. Near term earnings recovery is pegged to a few product opportunities going right. There are certain 7catalysts in FY22E, FY23E and FY27E. The company is diversifying into agro-chemicals where it is trying to replicate its Pharma success. The company has a strong balance sheet (supported by QIP) with INR 740 Crs cash on it. A large part of the earnings cycle is reflected in the share price performance. Valuations have also softened.

This note is focused on evaluating filings made for the US business.

Differentiated model: Natco's success in the US market was on the back of four key opportunities gTamiflu, gDoxil, gFosrenol, gCopaxone launched by its partners over a 11-month period from Dec-2016 to Oct-2017. These were litigation driven opportunities with limited competition. This model was replicated in the Indian market in the Hepatitis-C segment, where Natco became the first company to launch gSovaldi in Mar-2015, followed by other Hep-C launches (like gEpclusa in May-2017). Their presence and focus in high growth oncology also helped.

Profit expansion period FY14-18: Key opportunities helped US sales (including profit share) move up 8-9x from the levels of INR 100+/- crores in FY14-16 to INR 770 Crs in FY17 and INR 950 Crs in FY18. Domestic formulations sales jumped 4x over FY14-18. These limited competition, high margin opportunities helped profits move up ~7x over FY14-FY18.

Earning decline in FY19, to continue in FY20E: A major part of the early mover advantage on limited competition opportunities is already being capitalised, FY19 saw topline and profit dip due to incremental competition in key products (gCopaxone, gTamiflue) and segments (domestic Hep-C), and also a reasonably high base. For H1FY20, the company reported a sales/PAT decline of 8%/25% respectively. FY20E is likely to see YoY decline.

Summary: Natco has a strong history of executing limited competition opportunities. It has a strong balance sheet as well. In the near term, the earning pressure could continue because of challenges in the US business (competition in gTamiflu, pricing related issues in Copaxone), continuing erosion in high margin Hep-C portfolio in India, pricing related challenges in Onco portfolio. The possible near term opportunities are subject to litigation outcomes - like the gRevlimid launch in Canada and a potential launch in the agro-chemicals space. On the limited competition filings front, subject to litigation, there are a few interesting products that could get commercialised. The long term business capabilities in terms of capitalizing on limited competition opportunities are intact, with a few visible launches like gRevlimid in US in Mar-2022, gKyprolis in 2027.

Share performance, valuations: A large part of the earnings story is also reflected in Natco's share performance: From INR sub-300 in Dec-2014 to INR 1000 in July-2017. From INR 1000 in Jan-2018 to around INR 500 in July-2019 and INR 600 now. The stock is trading at a PER of 19x FY20E (consensus). Valuations have come off from the highs of the recent past.

In this note, we have evaluated US pipeline by mapping 16 filings. These products broadly fall into three categories: (a) Opportunities with case settlements and reasonably clear launch timelines - gRevlimid March-2022, gKyprolis 2027, gNexavar (likely launch post Jan-2020). (b) Filings which are not lucrative anymore, in our assessment - gZytiga, gSovaldi, gTarceva. and (c) Filings where the outcome is dependent on court verdict and is difficult to assess for now - gPomalyst, gTracleer. In terms of timelines, gAfinitor and gNexavar should be watched.

Figure-01: Financial Summary

Year to March (INR Cr)	FY14	FY15	FY16	FY17	FY18	FY19
Revenues (INR Cr)	739	825	1,042	2,020	2,185	2,095
Ch, YoY	*12%*	*12%*	*26%*	*94%*	*8%*	*-4%*
EBITDA (INR Cr)	179	196	266	683	928	795
EBITDA margin	*24%*	*24%*	*25%*	*34%*	*42%*	*38%*
PAT (INR Cr)	97	141	156	485	687	632
PAT margin	13%	17%	15%	24%	31%	30%
EPS (INR)	6	8	9	28	37	35
Ch, YoY	*41%*	*43%*	*5%*	*210%*	*34%*	*-7%*
RoACE (%)	15%	14%	17%	38%	33%	20%
RoAE (%)	16%	17%	15%	33%	29%	20%

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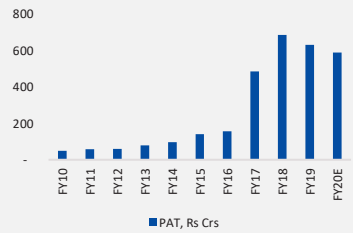
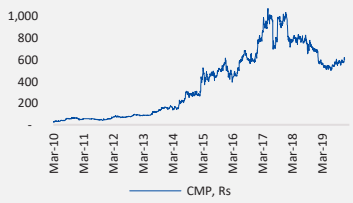
CMP: INR 625

M. Cap: INR 11,377 Crs

52-W H/L: INR 707/482

Rating: Not Rated





January 14, 2020

Revenue Mix

Natco has two key revenue verticals: (a) US: 41% of FY19 sales and (b) India formulations (37%). Further, the domestic formulations has two major parts: non-oncology (17% of sales) - primarily Hepatitis-C and oncology (20%).

Figure-02: Revenue Mix: Significant jump in FY17, subdued FY19

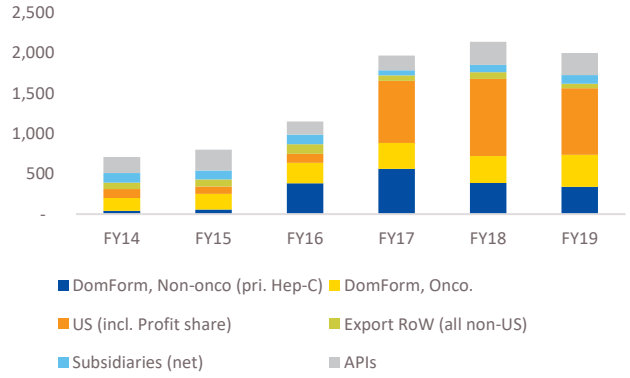
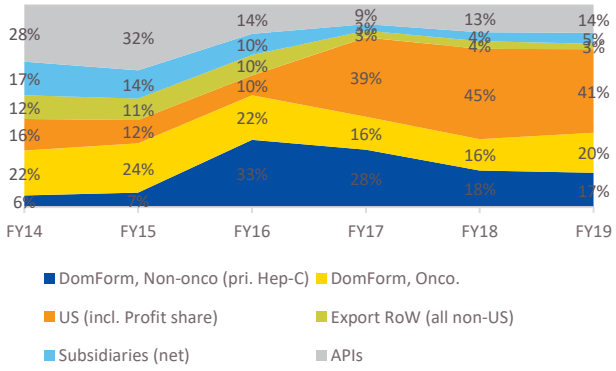


Figure-03: Revenue Mix: US 41%, Domestic Formulations: 37%



Differentiated model

Natco followed a different path for the US market – targeting select opportunities with limited competition translating into high margins and generating significant cash flows. The product portfolio was focused on complex products or litigation related opportunities.

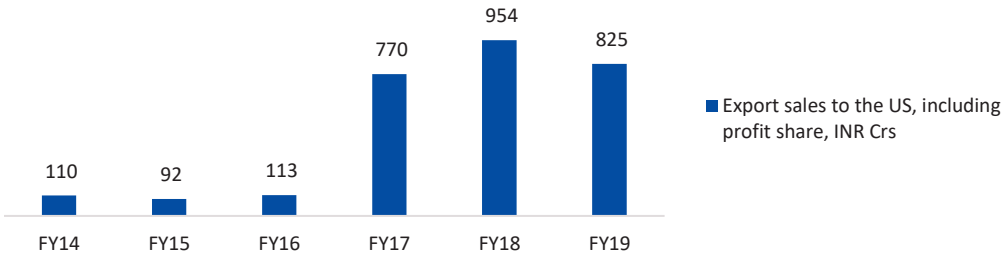
Natco's successfully delivered four key opportunities gTamiflu, gDoxil, gFosrenol, gCopaxone which the company commercalized through its partners over a 11-month period from Dec-2016 to Oct-2017.

Figure-04: Key launches in the US (through partners)

Brand	Tamiflu	Doxil	Fosrenol	Copaxone
Period since launch (as of Jan-2020)	3 years	2 years, 8 months	2 years, 5 months	2 years, 2 months
Launch Date	Dec-2016 (Q3FY17)	May-2017 (Q1FY18)	Aug-2017 (Q2FY18)	Oct-2017 (Q3FY18)
Natco's launch - first/second generic	First generic	Second generic	First generic	20mg – second, 40mg – first (major strength)
API	Oseltamivir	Liposomal Doxorubicin	Lanthanum Carbonate	Glatiramer Acetate
Indication	Flu/ Influenza A and B	Cancer	Hyperphosphatemia	Multiple Sclerosis (CNS)
Innovator	Marketing by Roche (Genentech), licensed from Gilead Sciences	J&J (Janssen Products)	Shire (owned by Takeda now)	Teva
Natco's Partner	Alvogen	Dr Reddy's	Lupin	Mylan

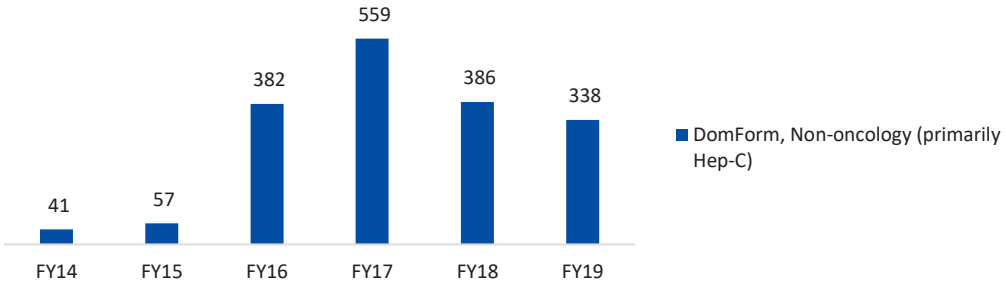
Key opportunities helped US sales (including profit share) move up 8-9x from the levels of INR 100+/ crores over FY14-16 to INR 770 Crs in FY17 and to INR 950 Crs in FY18.

Figure-05: US Sales (including profit share), INR Crores



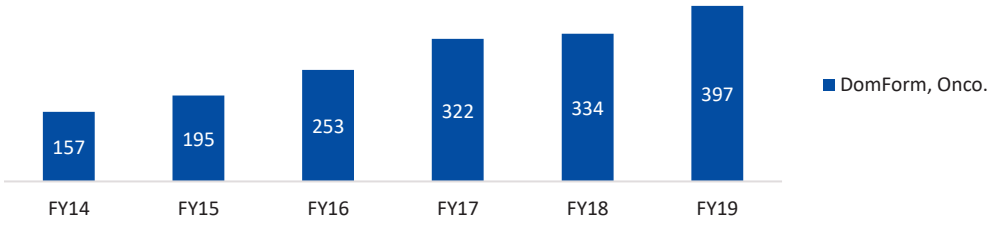
Natco replicated its limited competition US model for the Indian market in the Hepatitis-C segment, where it became the first company to launch gSovaldi (sofosbuvir) in Mar-2015, followed by other Hep-C launches like gEpclusa (sofosbuvir/velpatasvir) in May-2017.

Figure-06: Domestic Formulations, Non-Oncology (primarily Hepatitis-C), INR Crs



Unlike other players in the Indian market, who have diversified offerings across therapies, Natco has been primarily focused on the oncology segment.

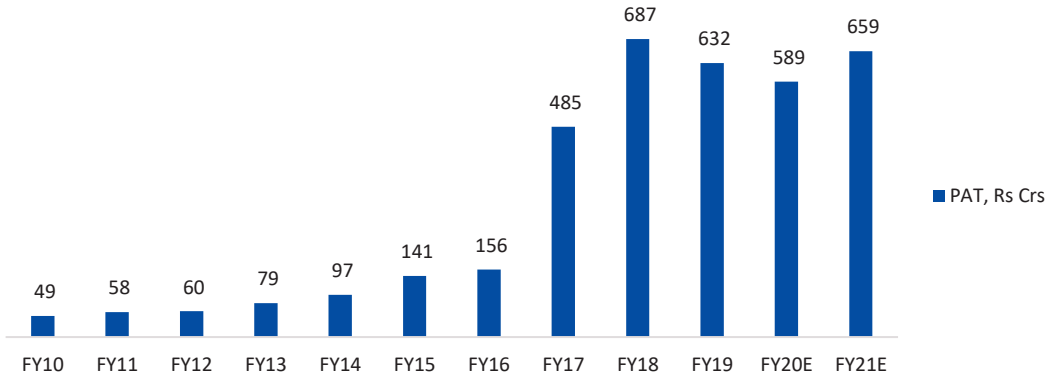
Figure-07: INR Crs. Domestic Oncology (20% of sales in FY19) stable and growing business. H1FY20 was weak though (21% decline YoY).



Earnings expansion till FY18, subdued FY19, FY20.

The differentiated model is reflected in a sharp profit jump of 4x from Rs 150 Crs in FY16 to Rs 690 Crs in FY18. Whilst a major part of the early mover advantage on limited competition opportunities was already being capitalized, FY19 saw topline and profit dip due to incremental competition in key products (gCopaxone, gTamiflue, domestic Hep-C) and a reasonably high base. For H1FY20, the company reported sales/PAT decline of 8%/25% respectively. FY20E is likely to see YoY decline. Growth recovery is expected in FY21E (consensus numbers).

Figure-08: Earnings trajectory – sharp jump from FY16-18; subdued FY19, FY20E



Earnings revision and stock performance

The stock has broadly followed the earnings upgrade/downgrade trajectory.

Figure-09: Sales revision (FY13E - 21E)

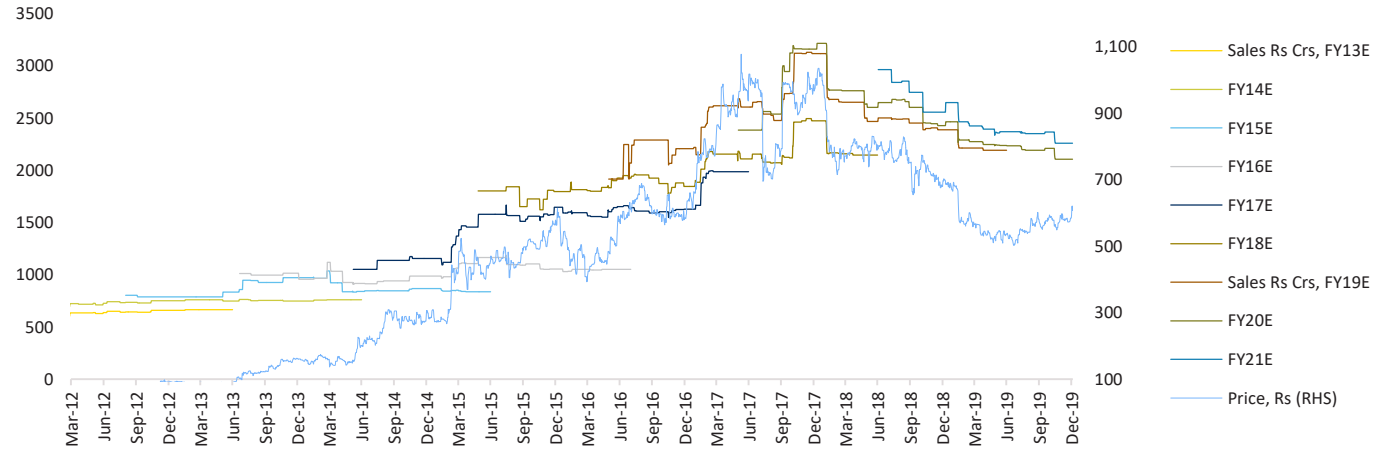


Figure-10: EBITDA revision (FY13E - 21E)

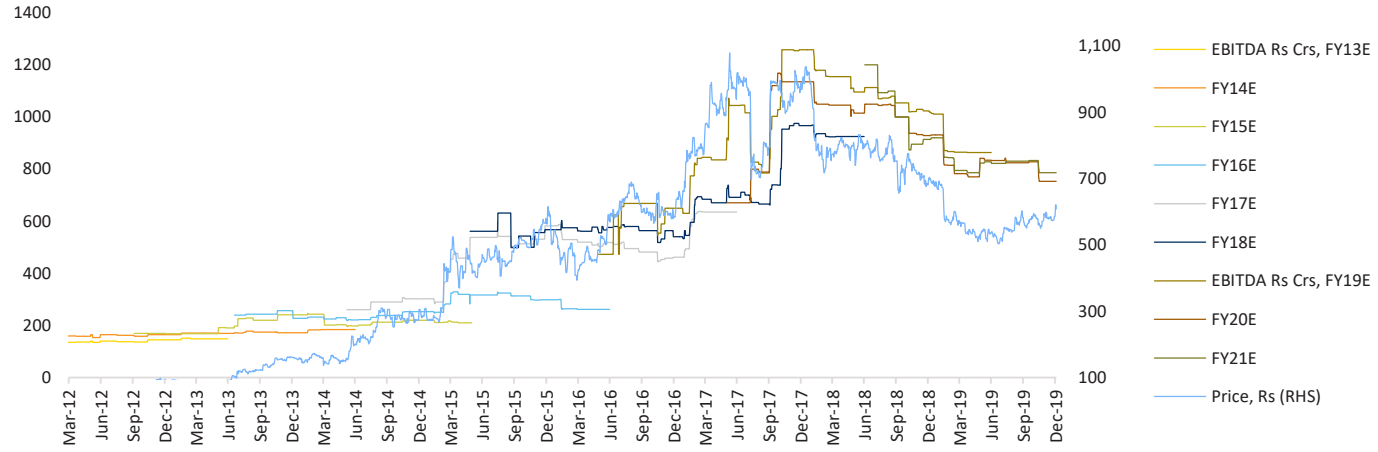
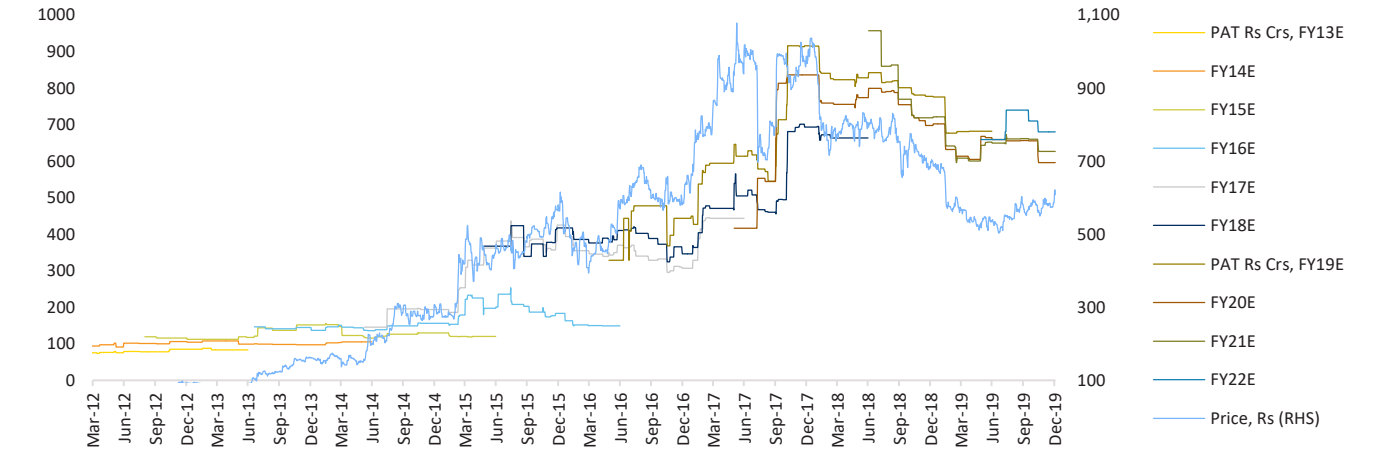


Figure-11: PAT revision (FY13E - 21E)



The downgrade cycle appears be bottoming out..

Figure-12: Sales revision (primarily FY19E, 20E)

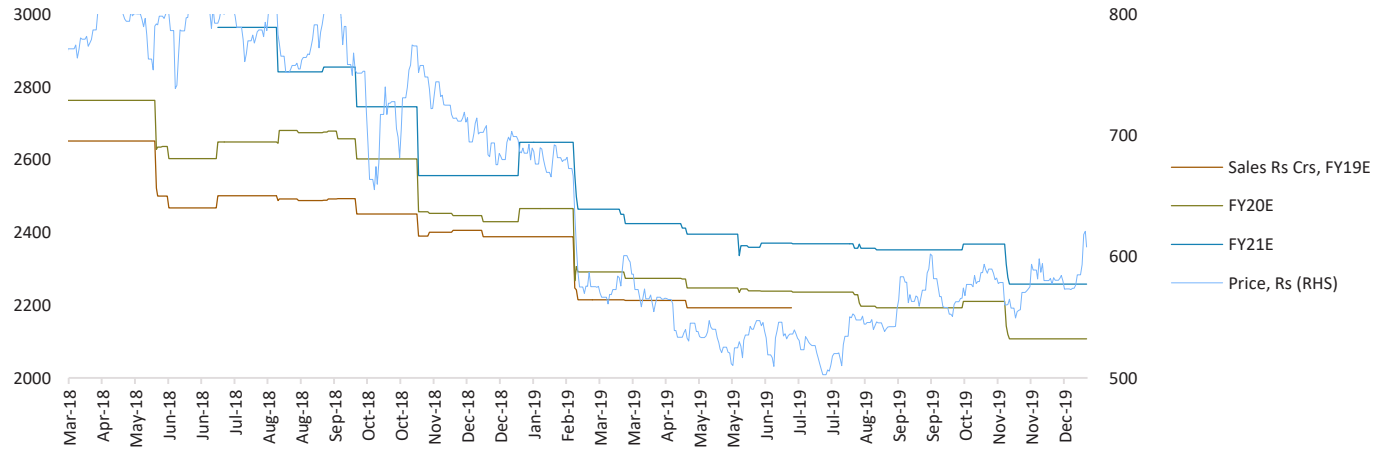


Figure-13: EBITDA revision (primarily FY19E, 20E)

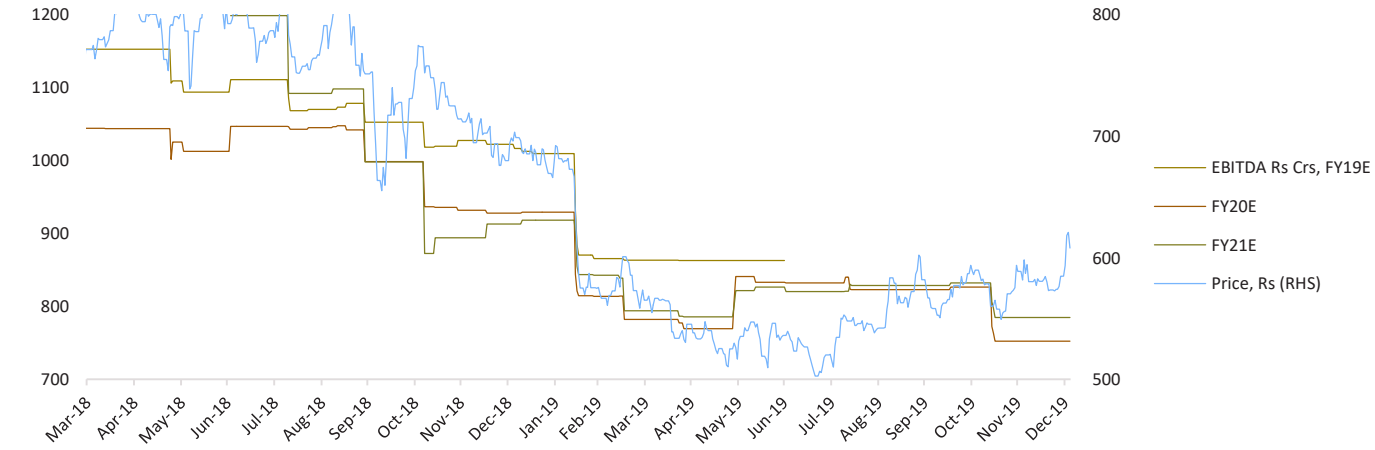
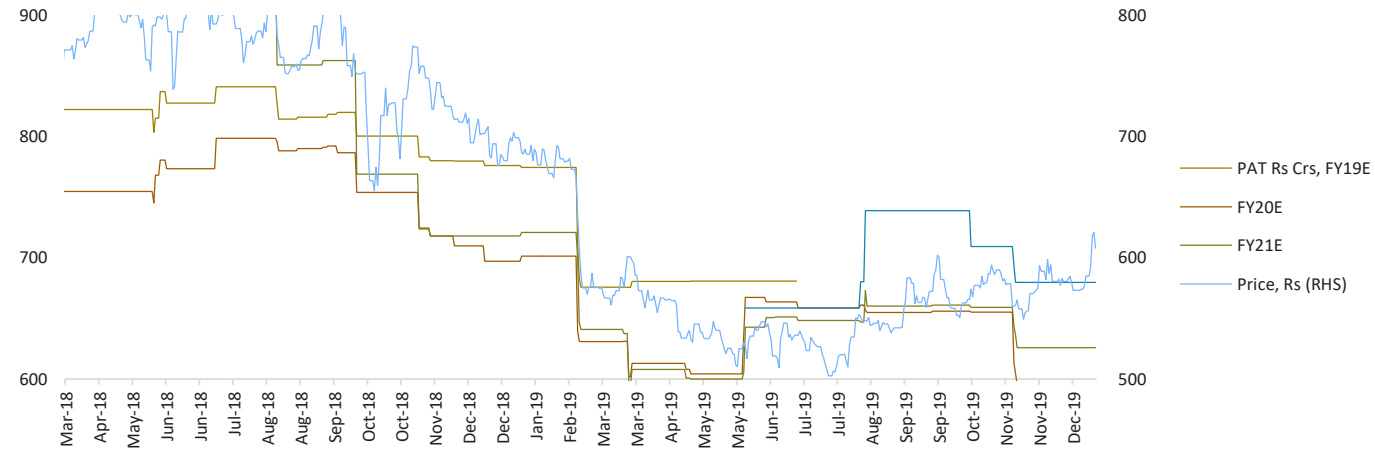


Figure-14: PAT revision (primarily FY19E, 20E)



Valuations:

Multiples have come off from the highs of the recent past

Figure-15: PE: 18x 1-Yr forward

Figure-16: EV/EBITDA: 15x 1-Yr forward

Figure-17: EV/Sales: 4.7x 1-Yr forward

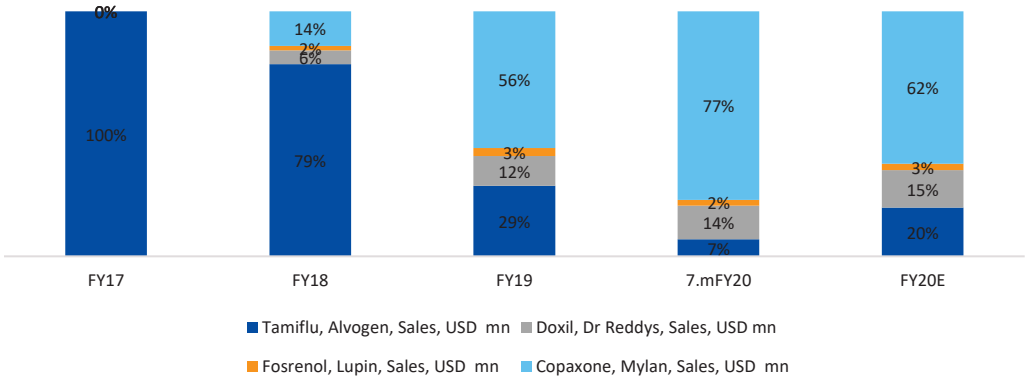
US BUSINESS

US Sales: Marketed Products

Natco focuses on limited competition, limited period opportunities. These opportunities are of both the types - complex and regular. gCopaxone / Glatiramer acetate for example, is a complex product whereas gTamiflu / Oseltamivir is a regular one.

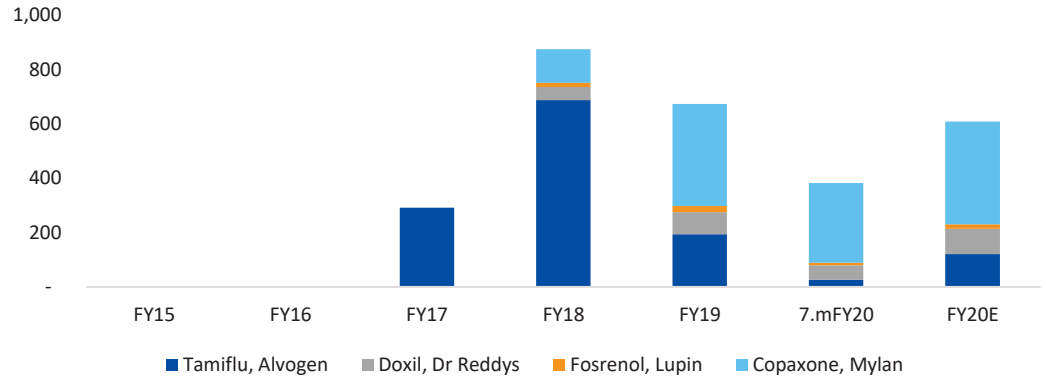
gTamiflue was the first and a major opportunity. gCopaxone is an important product from FY19 perspective.

Figure-18: Indicative contribution of four key drugs, BB



Note: Bloomberg numbers are only for indicative purpose. Actual numbers are significantly different from bloomberg numbers.

Figure-19: Indicative contribution of four key drugs



US filings Summary:

We have mapped 16 product filings. These products fall into three categories: (a) Opportunities with case settlements and reasonably clear launch timelines - gRevlimid March-2022, gKyprolis 2027, gNexavar (likely launch post Jan-2020). (b) Filings, which in our assessment are not lucrative anymore: gZytiga, gSovaldi, gTarceva. and (c) Filings which are diffecult to assess, where outcome is dependent on the court verdict - gPomalyst, gTracleer.

In terms of timelines, gAfinitor and gNexavar should be watched.

Figure-20: US Filings Summary

	Brand I API I Innovator	Comments
01	**Nexavar I Sorafenib I Bayer**	Settled. Likely launch anytime - after Jan-2020 (API patent expiry).
02	**Revlimid I Lenalidomide I Celgene**	Case settled. Volume-limited launch in Mar-2022. Unlimited quantity from Jan 31, 2026. Patent expiry April-2027.
03	**Kyprolis I Carfilzomib I Amgen**	Settled in May-2019. Launch in 2027. Three strengths, sole FTF for one of the strengths (10mg).
04	**Treanda I Bendamustine I Teva (Cephalon)**	Settled earlier, USFDA guidelines on another drug with the same API would mean that the launch would be pushed from an earlier expectation of Nov-2019 to Dec-2022.
05	**Zortress I Afinitor I Everolimus I Novartis**	Afinitor – No clarity yet. Launch in the near future is a likely scenario. Two generic players with strengths other than that of Natco's filing are in the market now. Zortress – Under litigation.
06	**Aubagio I Teriflunomide I Sanofi**	Appears to be an extremely competitive opportunity.
07	**Sovaldi I Sofosbuvir I Gilead Sciences**	No more a meaningful opportunity.
08	**Zytiga I Abiraterone I J&J**	Generics have started to enter from Nov-2018, several in market already. No more an opportunity.
09	**Tarceva I Erlotinib I Roche (Astellas)**	No longer an opportunity. Mylan and Teva have already launched generic version in May-2019.
10	**Tykerb I Lapatinib I Novartis (Earlier GSK)**	No clarity on the legal status despite it being 8+ years old filing.
11	**Imbruvica I Ibrutinib I AbbVie + J&J**	Currently under litigation (tablet form). Limited attractiveness in case of success. Recent filing, not a near-term opportunity.
12	**Tracleer I Bosentan I J&J (Actelion)**	Subject to litigation outcome/settlement. If successful could be a small opportunity. Generic versions launched for two other strengths. Natco is looking for a lower strength pediatric version.
13	**Pomalyst I Pomalidomide I Celgene**	Under litigation. 30-month stay ends on Aug.08, 2020.
14	**Gilenya I Fingolimod I Novartis**	No specific update from the innovator/ generic companies. Subject to litigation/settlement, the launch could be in CY20/CY21.
15	**Jevtana I Cabazitaxel I Sanofi**	Under litigation. Outcome dependent on court's decision / settlement. If Natco wins the litigation or if there is any settlement, the launch timeline could be around Sept-2021.
16	**Lonsurf I Trifluridine-Tipiracil I Taiho (Otsuka)**	Litigation just began. Subject to legal outcome, but not a near term opportunity.

Drug Profiles:

	Products

Marketed Products

01. Tamiflu I Oseltamivir I Roche (Genentech) Gilead I Dec-2016 (Q3FY17)
02. Doxil I Liposomal-Doxorubicin I J&J (Janssen) I May-2017 (Q1FY18)
03. Fosrenol I Lanthanum Carbonate I Takeda (Shire) I Aug-2017 (Q2FY18)
04. Copaxone I Glatiramer Acetate I Teva I Oct-2017 (Q3FY18)

Filings (Pipeline)

01. Nexavar I Sorafenib I Bayer
02. Revlimid I Lenalidomide I Celgene
03. Kyprolis I Carfilzomib I Amgen
04. Treanda I Bendamustine I Teva (Cephalon)
05. Zortress I Afinitor I Everolimus I Novartis
06. Aubagio I Teriflunomide I Sanofi
07. Sovaldi I Sofosbuvir I Gilead Sciences
08. Zytiga I Abiraterone I J&J
09. Tarceva I Erlotinib I Roche (Astellas)
10. Tykerb I Lapatinib I Novartis (Earlier GSK)
11. Imbruvica I Ibrutinib I AbbVie + J&J
12. Tracleer I Bosentan I J&J (Actelion)
13. Pomalyst I Pomalidomide I Celgene
14. Gilenya I Fingolimod I Novartis
15. Jevtana I Cabazitaxel I Sanofi
16. Lonsurf I Trifluridine-Tipiracil I Taiho (Otsuka)

Tamiflu
oseltamivir

Tamiflu was the first key opportunity for Natco. The product was launched in Dec-2016 (Q3FY17) by Natco's partner - Alvogen. The drug started to contribute from Q4FY17. Zydus Cadila launched its generic in Feb-2017. The product, for Natco recorded peak sales in FY18. FY19 saw a significant increase in competition and sales declined as a result. There were seven generic companies till Sept-2019 when Teva entered. This would mean higher competitive pressure going ahead (in FY20). The indicative market share of Alvogen/Natco (value) based on Bloomberg reported numbers is around 20% now Vs 48% in FY18. Alvogen (Natco) and Zydus, have similar market shares. Macleods is gaining the share aggressively. Alembic Pharma which had received ANDA approval in June-2019, would also come in now. This would mean higher pressure going ahead. Roche numbers for CY18/19E/20E: US 170/40/20 mn.

Figure-21: Tamiflu / Oseltamivir snapshot

Brand	Tamiflu
API	Oseltamivir
Innovator/Marketer	Roche (Genentech), licensed from Gilead Sciences
Indication	Flu (Influenza A and Influenza B). Anti-viral
Dosage Form	Capsules, Powder for oral suspension
Strengths (innovator)	Capsule: 30 mg, 45 mg, 75 mg Powder for oral suspension: 360 mg oseltamivir base (constituted to a final concentration of 6 mg/mL)
Initial Innovator Approval	Oct-1999
Natco's partner	Alvogen
Natco's filing	Para-IV / FTF
Filed (Natco)	in Feb-2011
Settlement	Yes, Natco + Alvogen settled with Gilead and Roche
Settlement timelines	Settled in 'Dec-2015
Natco's generic launch	Dec-2016
First generic	Yes, Natco (Alvogen) was the first generic
DMFs	Total 8 DMFs: Cipla, Hetero, Lupin, Macleods, MSN, Mylan, Raks, Solara
Generic companies involved in patent litigation	Natco, Lupin
Market Size	Roche CY15/16 Tamiflu sales: USD 550/470 mn
	Roche, CY18 Tamiflu US Sales: USD 170 mn
	As per IQVIA, oseltamivir total market size (capsule) was around USD 650 in CY18.
Competitive Landscape	Crowded market with eight generic players (Teva recently entered Sept-2019). Additionally, Alembic Pharma which had received ANDA approval in June-2019, would also come in.
Outlook	Competitive pressure has been rising, likely to intensify going ahead.

Figure-22: Tamiflu, US Sales, Roche, USD mn

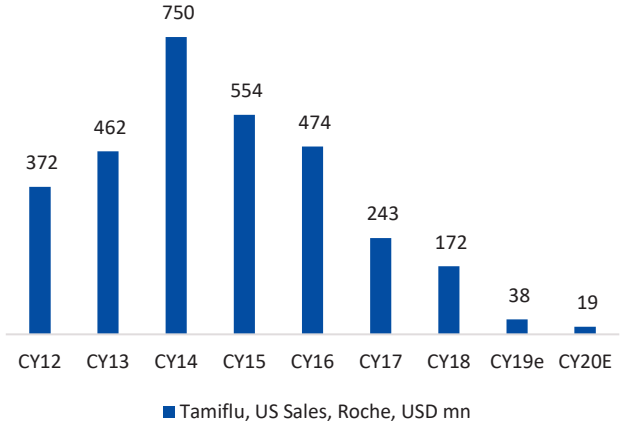


Figure-23: Tamiflu. US. Brand and generic monthly sales, USD mn (BB numbers, indicative)

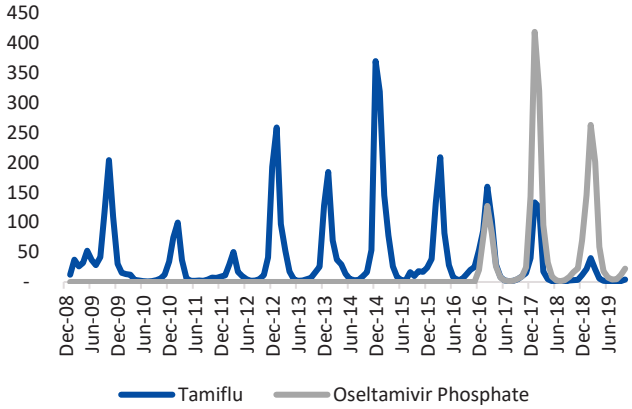


Figure-24: Tamiflu. US. Brand and generic FY sales, USD mn (BB numbers, indicative)

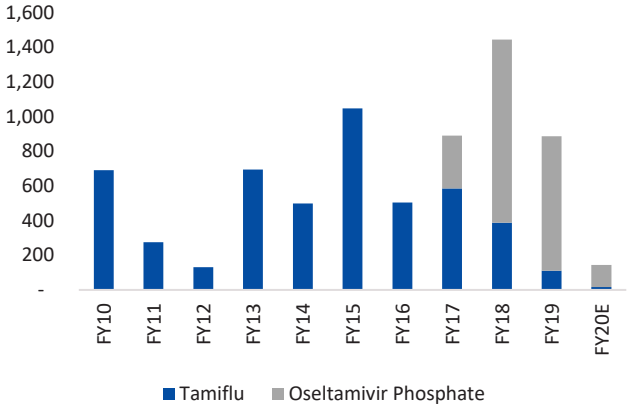


Figure-25: Tamiflu generic, Alvogen monthly sales, USD mn

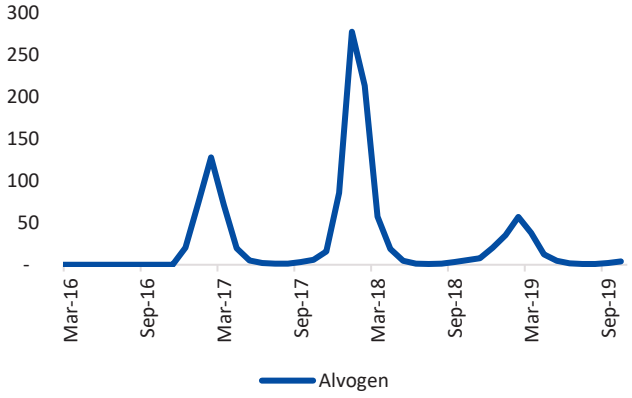


Figure-26: Indicative market share (value, BB numbers)

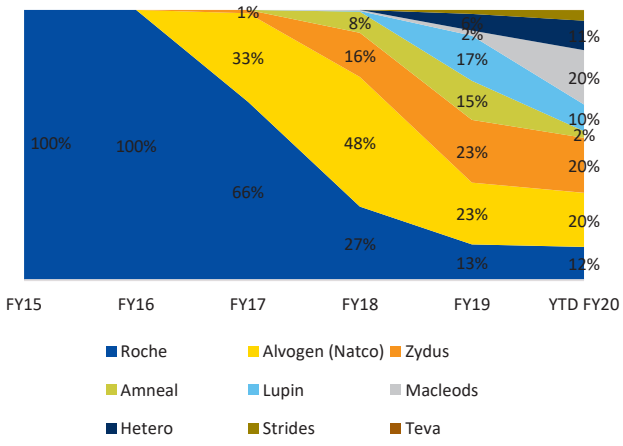


Figure-27: Tamiflu generic, Alvogen Sales, USD mn

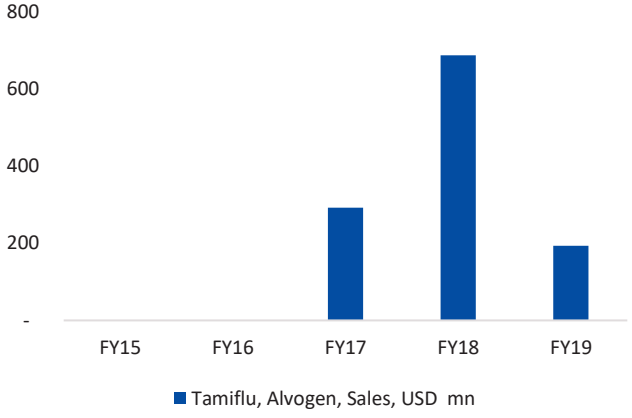


Figure-28: Indicative market share (value, Bloomberg numbers)

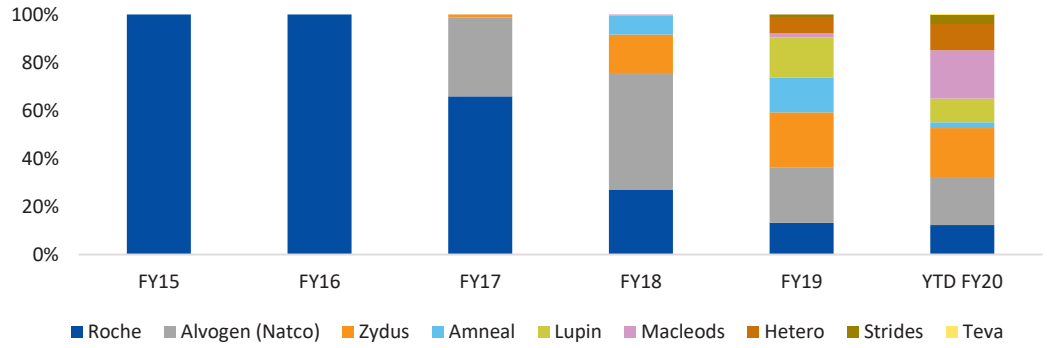


Figure-29: Oseltamivir DMFs

Submit Date	Holder (Oseltamivir)
5/29/2008	Cipla Ltd
7/8/2009	Solara A Pharma Sciences Ltd
6/15/2010	MSN Pharmachem Private Ltd
9/29/2013	Macleods Pharmaceuticals Ltd
11/30/2015	Mylan Laboratories Ltd
4/13/2016	Lupin Ltd
3/16/2016	Hetero Labs Ltd
11/28/2018	Raks Pharma Pvt Ltd

Figure-30: Oseltamivir Patent Litigation

Submit Date	ANDA Filer	Oseltamivir Patent no.
D.N.J. Mar. 15, 2011	Natco Pharma Ltd.; Natco Pharma Inc.	5,763,483
D. Del. Mar. 14, 2011	Natco Pharma Ltd.; Natco Pharma Inc.	5,763,483
D.N.J. Aug. 29, 2011	Natco Pharma Ltd.; Natco Pharma Inc.	5,763,483
D. Md. Sept. 16, 2015	Lupin Pharmaceuticals Inc.; Lupin Atlantis Holdings SA; Lupin Ltd.	5,763,483

Doxil
doxorubicin

Natco's partner - Dr Reddys, launched the generic version in May-2017. Sun Pharma was already in the market. From Feb-2012, the USFDA had exercised enforcement discretion for temporary controlled importation of Sun Pharma/Caraco's Lipodox (without approval), an alternative to Doxil. Sun Pharma got approval in Feb-2013.

Figure-31: Doxil / Doxorubicin snapshot

Brand	Doxil
API	Liposomal Doxorubicin
Innovator/Marketer	J&J (Janssen Products)
Indication	Cancer
Dosage Form	Injection
Strengths (innovator)	20 mg/10 mL (2 mg/mL) 50 mg/25 mL (2 mg/mL)
Initial Innovator Approval	Nov-1995
Natco's partner	Dr. Reddy's (co-development and marketing partner)
Natco's filing	----------
Filed (Natco)	----------
Settlement	
Settlement timelines	
Dr Reddy's (Natco) generic Launch	Aug-2017 (Q2FY18)
First generic	Sun Pharma was already present.
DMFs	Total 15+ DMFs, 10 active. Pharmacia And Upjohn (Pfizer), DZD (HEZE), Meiji Seika, Microbiopharm Japan, Olon Spa, RPG Life, Sterling Biotech, Synbias Pharma Ag, Teva, Zhejiang Hisun
Generic companies involved in patent litigation	BB Law - no mention of any company
Market Size	The Doxil brand and generic had US sales of USD 196 million for the 12 months ending in March 2017, according to IMS Health.
Competitive Landscape	Three key generic players: Sun, Dr Reddys, Baxter + Blupoint Labs
Outlook	Stable Bloomberg shows Baxter sales for the month of Oct-2019.

Figure-32: Doxil / Doxorubicin - Entry of generics: monthly numbers, Sun Pharma, Dr Reddys (Natco) – USD mn

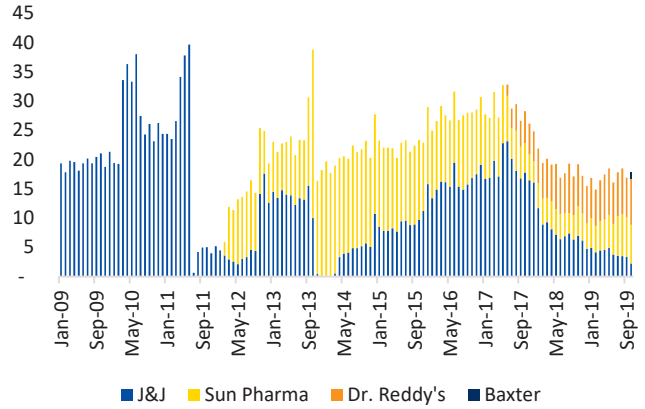


Figure-33: Doxil / Doxorubicin - Entry of generics: Sun Pharma, Dr Reddys (Natco)

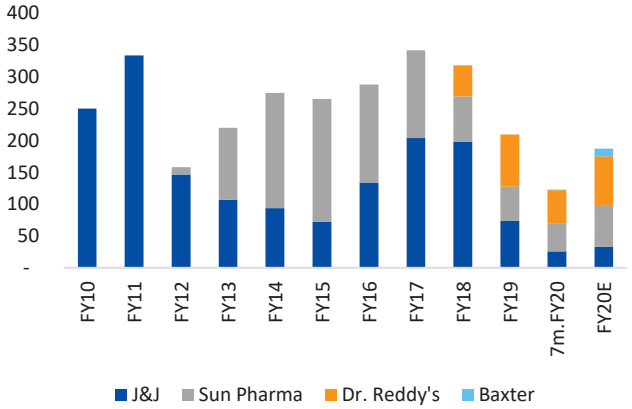


Figure-34: Doxil / Doxorubicin – Indicative m/s (value) Bloomberg

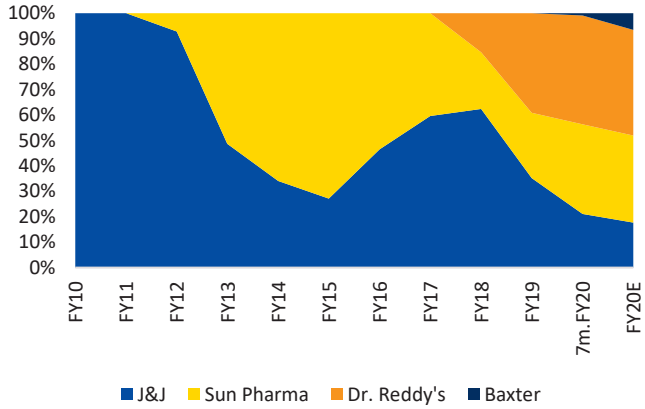
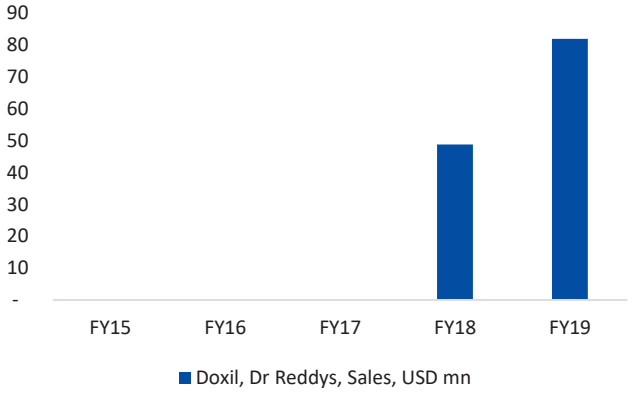


Figure-35: Doxil, Doxorubicin: Indicative sales performance (BB)



Note: m/s – market share, BB – Bloomberg

Figure-36: Doxorubicin DMFs

Submit Date	Holder (Doxorubicin)
4/27/1973	Pharmacia And Upjohn Co (Pfizer Inc)
4/30/1998	Meiji Seika Pharma Co Ltd
4/30/1998	Microbiopharm Japan Co Ltd
9/1/1998	Teva Pharmaceutical Industries Ltd
9/1/1998	Zhejiang Hisun Pharmaceutical Co Ltd
10/9/2002	Synbias Pharma Ag
4/5/2011	Sterling Biotech Ltd
9/9/2013	Zhejiang Hisun Pharmaceutical Co Ltd
11/16/2015	Olon Spa
11/11/2016	DZD (Heze) Pharmaceutical Co Ltd

Fosrenol
lanthanum carbonate

Natco's partner - Lupin launched the drug in Aug-2017. At the same time, Prosco Labs launched the Authorised Generic version. It has been a two generic player market since then. Prosco holds about 50% market share, 35% with Lupin, the rest with Takeda (Shire). Market declined 38% YoY in FY19. Stable outlook. Although it's a very small product compared to Tamiflu or Copaxone.

Figure-37: Fosrenol / Lanthanum Carbonate snapshot

Brand	Fosrenol
API	Lanthanum Carbonate
Innovator/Marketer	Shire (Takeda now)
Indication	to reduce serum phosphate in patients with End Stage Renal Disease (ESRD)
Dosage form	Chewable Tablets
Strengths	500 mg (base), 750 mg (base), and 1000 mg (base)
Initial Innovator Approval	Oct-2004
Natco's partner	Lupin
Natco's filing	-----
Filed (Natco)	-----
Settlement	-----
Final Approval	August 14, 2017
Lupin's (Natco) generic Launch	August 30, 2017 (Q2FY18)
First generic	Yes
DMFs	Total 9 DMFs, 7 active Mylan, Natco, Excella GmbH, Unimark Remedies, Signa Sa De Cv (Apotex), Symed Labs
Generic companies involved in patent litigation	Alkem, Apotex
Size (latest available data on approval date – Aug-2017)	USD 122 mn
Competitive Landscape	Two generic players: Lupin (Natco) and Prasco Labs (Authorised Generic)
Outlook	Stable
API	Lanthanum Carbonate

Figure-38: Fosrenol / Lanthanum generic launches – Lupin (Natco), Prasco (AG). Monthly sales

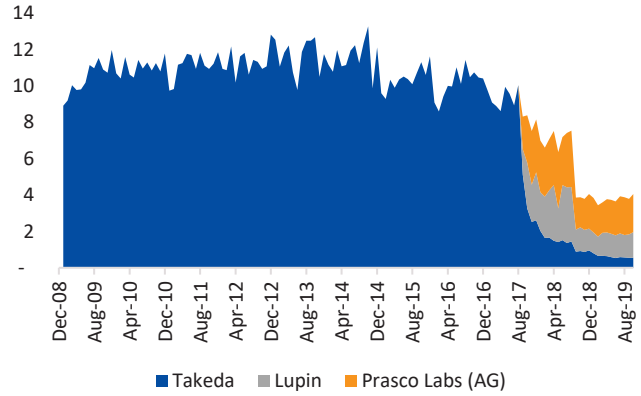


Figure-39: Fosrenol / Lanthanum generic launches – Lupin (Natco), Prasco (AG)

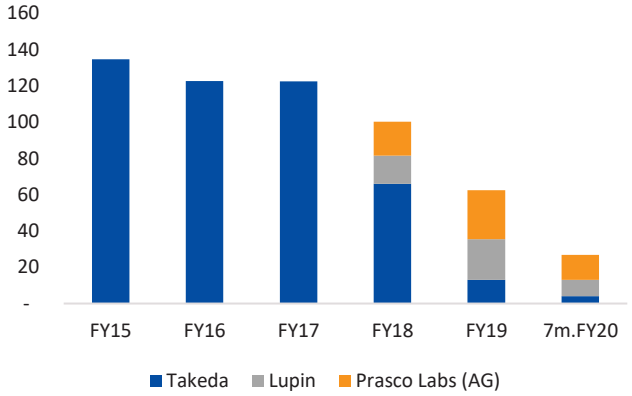


Figure-40: Fosrenol / Lanthanum indicative performance (BB)

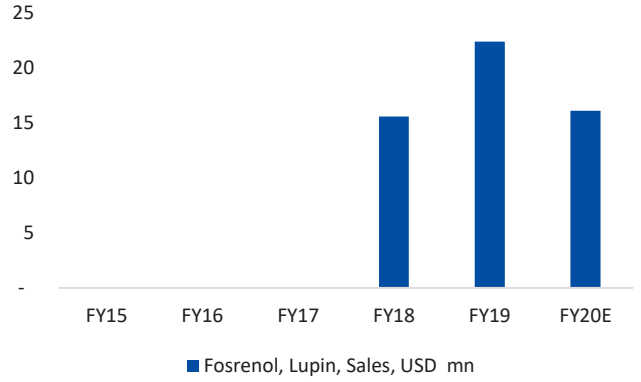


Figure-41: Fosrenol / Lanthanum indicative m/s (value, BB)

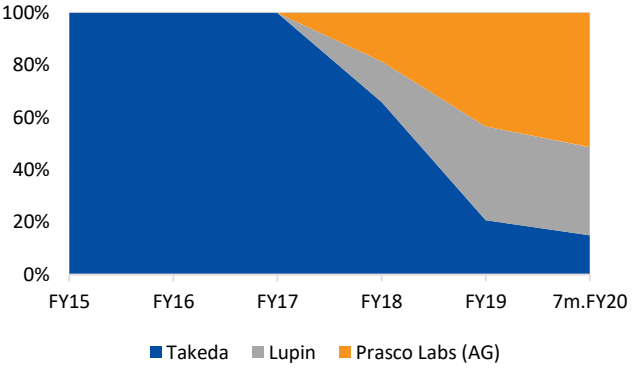


Figure-42: Lanthanum Carbonate DMFs

Submit Date	Holder (Lanthanum Carbonate)
9/5/2008	Mylan Laboratories Ltd
10/2/2008	Natco Pharma Ltd
10/17/2008	Excella Gmbh And Co Kg
11/5/2009	Unimark Remedies Ltd
6/5/2014	Signa Sa De Cv
4/21/2014	Symed Labs Ltd
12/11/2018	Mylan Laboratories Ltd

Figure-43: Lanthanum Carbonate Patent Litigation

Submit Date	ANDA Filer	Lanthanum Carbonate Patent no.
S.D.N.Y. Jan 13, 2011	Alkem Laboratories Ltd.	5,968,976; 7,465,465
N.D. Ill. Jan 12, 2011	Alkem Laboratories Ltd.	5,968,976; 7,465,465
D. Del. Nov. 12, 2015	Apotex, Inc.; Apotex Corp.	7,381,428; 7,465,465; 5,968,976

Copaxone
glatiramer acetate

There are two strengths 20mg/ml and 40mg/ml. The market had shifted towards 40mg/ml from Aug-2014. Natco's partner Mylan launched the generic version (both strengths) in Oct-2017 (Q3FY18). Sandoz (Novartis) had launched the 20mg version in June-2015 but was late in launching the important 40mg version (Feb-2018).

Teva reacted to the competition, and offered payer rebates (discount). This is the key reason why Teva still controls a large market. Between Mylan and Sandoz, Mylan has been able to capture the larger part.

Mylan in its Q3CY19 call highlighted that, the company has strong demand with current market share exceeding 35%. The company continues to see uptick on growth as the new prescriptions are now bigger than 40% market share. Bloomberg - indicative market shares (value terms): Teva: 76%, Mylan: 17%, Sandoz: 7%

Even now, there are just two generic players Sandoz (Novartis) and Mylan (Natco). Hereafter, since the other big ticket opportunity – gTamiflu is under pressure, the contribution of gCopaxone revenue in the overall pie has gone up in FY19, and this will further increase in FY20E.

Earlier (in June-2019), Dr Reddy's had indicated that it would launch generic Copaxone in H1FY20. However, it received CRL (complete response letter) in Aug-2019. The company is in the process of answering the queries. With this, Dr Reddy's the launch expectation is shifted to FY21.

Complexity of Copaxone: Glatiramer acetate is more complex than a polypeptide or protein derived from a biotechnological process. Because, it is a heterogeneous mixture of up to 1029 possible immunogenic polypeptides of varying sequences and sizes and are extremely difficult / almost impossible to isolate, quantify and sequence, or fully characterize, even with highly discriminatory analytical methods.

The FDA approved generic versions of 40 mg/mL in October 2017 and February 2018 and a second generic version of 20 mg/mL in October 2017 in the United States.

Figure-44: Copaxone / Glatiramer Acetate snapshot

Brand	Copaxone
API	Glatiramer Acetate
Innovator/Marketer	Teva
Indication	CNS - Multiple sclerosis (MS)
Dosage Form	Injection
Strengths (innovator)	20mg/mL and 40mg/mL
Initial Innovator Approval	Dec-1996
Natco's partner	Mylan
Mylan's first generic launch - both the strengths (40, 20)	05-Oct-2017
Version	AP rated
40 mg/mL	3-times-a-week
20 mg/mL	once-daily
Final approval	04-Oct-2019
First generic	40mg was first generic from Mylan
DMFs	Total 5 DMFs: Dr Reddys, Ambiopharm, Corden Pharma Colorado, Hybio Pharma, Gland Pharma
Generic companies involved in patent litigation	Natco, Mylan (Natco's partner), Sandoz (Novartis), Synthon, Apotex, Momenta, Dr. Reddy's, Amneal, Pfizer
Market opportunity as on 04-Oct-2017 (approval/launch date)	20 mg/mL : USD 700 mn 40mn/mL : USD 3.64 bn Combined: USD 4 bn 12-m July-2017
Market opportunity as on 04-Oct-2019 (approval/launch date)	20 mg/mL : USD 527 mn 40mn/mL : USD 2.86 bn Combined: USD 4 bn 12-m Aug-2018 (IQVIA)
Patient pool (as on Oct-2017)	Approximately 400,000 individuals in the U.S. have MS and relapsing MS accounts for 85% of initial MS diagnoses.
Copaxone advantage	Copaxone is the most prescribed MS treatment for relapsing forms of MS in the United States
Competitive landscape	Only two generic players - Mylan and Sandoz
Outlook	The outlook for Mylan is positive

Figure-45: Copaxone, Teva - shift from 20mg/ml to 40mg/ml

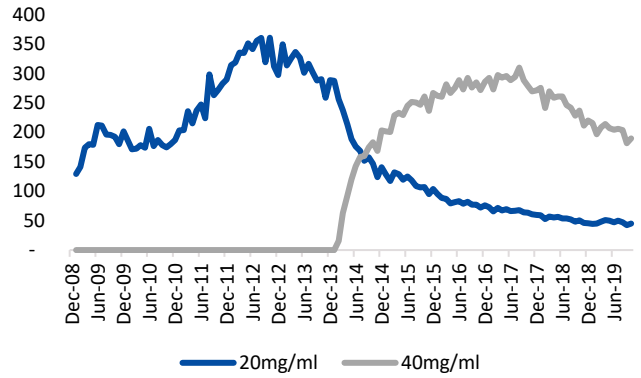


Figure-46: Copaxone, Teva - shift from 20mg/ml to 40mg/ml

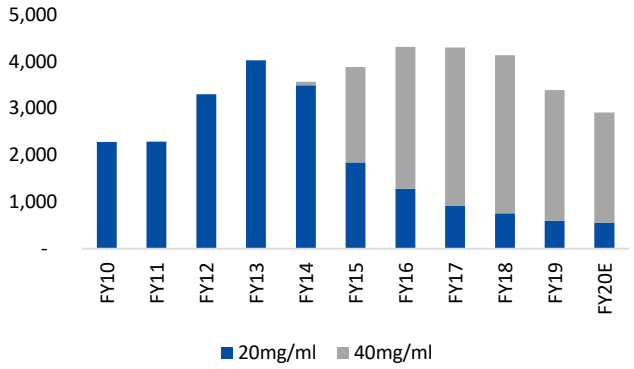


Figure-47: Generic launches by Sandoz and Mylan (Natco), monthly numbers BB

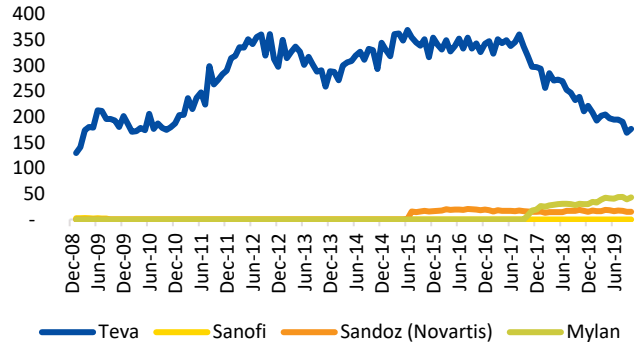


Figure-48: Copaxone: Indicative m/s (value)

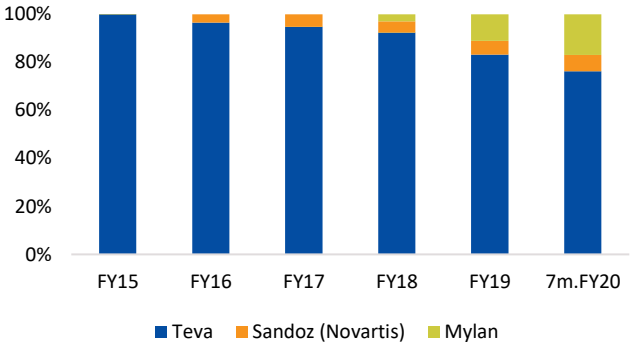


Figure-49: Copaxone: Indicative m/s (value), Mylan (Natco) Vs Sandoz

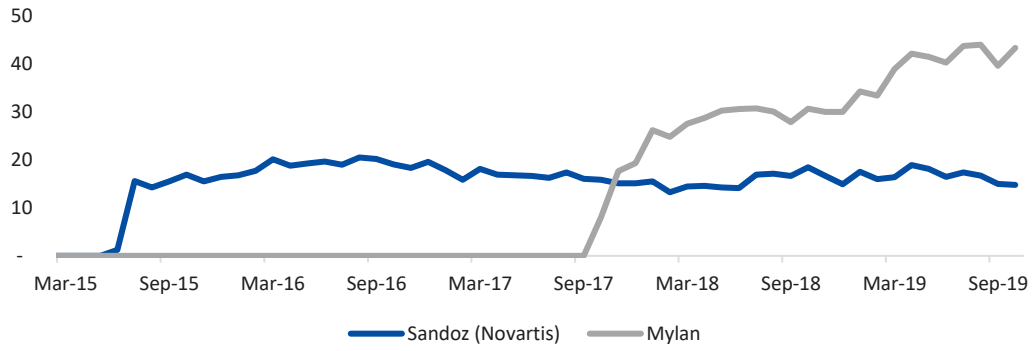


Figure-50: Glatiramer Acetate Indicative pricing

				Discount to Teva	
One month supply, WAC, USD	Teva (original)	Mylan	Sandoz	Mylan	Sandoz
20mg	7,114	1,950	1,500	73%	79%
40mg	5,832	1,950	1,500	67%	74%

WAC: Wholesale Acquisition Cost

Figure-51: US Copaxone Sales for Teva, USD mn

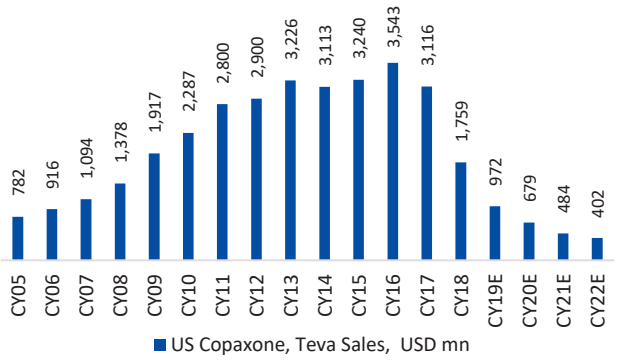


Figure-52: US Copaxone Sales for Teva, USD mn

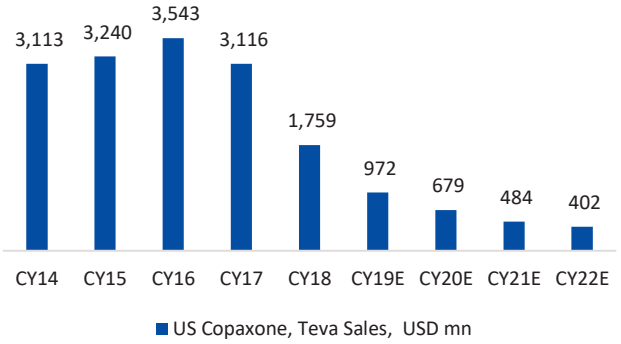


Figure-53: Glatiramer Acetate DMFs

Submit Date	Holder (Glatiramer Acetate)
3/24/2012	Dr Reddys Laboratories Ltd
9/27/2012	Ambiopharm Inc
12/12/2013	Corden Pharma Colorado Inc
12/25/2014	Hybio Pharmaceutical Co Ltd
9/12/2018	Gland Pharma Ltd

Figure-54: Glatiramer Acetate Patent Litigation

Date	ANDA Filer	Glatiramer Acetate Patent no.
S.D.N.Y. Aug. 28, 2008	Sandoz, Inc.; Sandoz Int'l GmbH; Novartis AG; Momenta Pharmaceuticals, Inc.	6,054,430;6,620,847; 6,939,539;7,199,098
S.D.N.Y. Oct. 16, 2009	Mylan Pharmaceuticals Inc.; Mylan Inc.; Natco Pharma Ltd.	5,981,589; 6,054,430;6,342,476; 6,362,161;6,620,847; 6,939,539;7,199,098
N.D. W. Va. Nov. 4, 2009	Mylan Pharmaceuticals Inc.; Mylan Inc.; Natco Pharma Ltd.	5,981,589; 6,054,430;6,342,476; 6,362,161;6,620,847; 6,939,539;7,199,098
S.D.N.Y. Dec. 10, 2009	Sandoz Inc.; Sandoz Int'l GmbH; Sandoz AG; Novartis AG; Momenta Pharmaceuticals, Inc.	6,514,938; 7,074,580;7,163,802; 7,615,359
S.D.N.Y. Sept. 20, 2010	Mylan Pharmaceuticals Inc.; Mylan Inc.; Natco Pharma Ltd.	6,514,938; 7,074,580;7,163,802; 7,615,359
E.D.N.C. Apr. 4, 2012	Synthon Pharmaceuticals, Inc.; Synthon Holding BV; Synthon BV; Synthon SRO	7,199,098; 6,939,539; 6,054,430; 6,620,847; 5,981,589; 6,342,476; 6,362,161
S.D.N.Y. Apr. 3, 2012	Synthon Pharmaceuticals, Inc.; Synthon Holding BV; Synthon BV; Synthon SRO	7,199,098; 6,939,539; 6,054,430; 6,620,847; 5,981,589; 6,342,476; 6,362,161
D.N.J. Sept. 11, 2014	Dr. Reddy's Laboratories Ltd.; Dr. Reddy's Laboratories Inc.; Sandoz Inc.; Momenta Pharmaceuticals Inc.	8,232,250; 8,399,413
N.D. W. Va. Oct. 7, 2014	Mylan Pharmaceuticals Inc.; Mylan Inc.; Natco Pharma Ltd.	8,232,250; 8,399,413
D. Del. Oct. 6, 2014	Mylan Pharmaceuticals Inc.; Mylan Inc.; Natco Pharma Ltd.	8,232,250; 8,399,413
D. Del. Nov. 18, 2014	Synthon Pharmaceuticals Inc.; Synthon BV; Synthon SRO Blansko	8,232,250; 8,399,413
D.N.J. Jan. 22, 2015	Synthon Pharmaceuticals Inc.; Synthon BV; Synthon SRO Blansko	5,800,808
D.N.J. Jan. 22, 2015	Dr. Reddy's Laboratories Ltd.; Dr. Reddy's Laboratories Inc.	5,800,808
D. Del. Feb. 3, 2015	Amneal Pharmaceuticals LLC	8,945,063
D. Del. April 10, 2015	Dr. Reddy's Laboratories Ltd.; Dr. Reddy's Laboratories Inc.; Mylan Pharmaceuticals Inc.; Mylan Inc.; Sandoz Inc.; Momenta Pharmaceuticals Inc.; Synthon Pharmaceuticals Inc.; Synthon BV; Synthon SRO; Amneal Pharmaceuticals LLC	8,969,302
D. Del. Apr. 19, 2016	Apotex Corp.; Biocon Ltd.,	8,232,250; 8,399,413; 8,969,302; 9,155,776
D. Del. Dec. 19, 2016	Dr Reddy's Laboratories Ltd.; Dr Reddy's Laboratories Inc.; Mylan Pharmaceuticals Inc.; Mylan Inc.; Sandoz, Inc.; Momenta Pharmaceuticals, Inc.; Synthon Pharmaceuticals Inc.; Synthon B.V.; Synthon s.r.o.; Synthon Pharmaceuticals Inc.; Pfizer Inc.; Amneal Pharmaceuticals LLC; Amneal GmbH; Biocon Ltd.; Apotex Corp.	9,402,874
D. Del. Jan. 25, 2017	Amneal Pharmaceuticals LLC; Amneal Pharmaceuticals Company GmbH	9,155,775
D.N.J. Jan. 25, 2017	Dr. Reddy's Laboratories, Ltd.; Dr. Reddy's Laboratories, Inc.	9,155,775
S.D.N.Y. Jan. 17, 2017	Pfizer, Inc.; Synthon B.V.; Synthon Pharmaceuticals, Inc.; Synthon S.R.O.	9,155,775
N.D. W. Va. Jan. 17	Mylan Inc.; Mylan Pharmaceuticals Inc.; Natco Pharma Ltd.	9,155,775
D. Del. Feb. 2, 2017	Momenta Pharmaceuticals, Inc.; Teva Pharmaceutical Industries Ltd.; Teva Neuroscience, Inc.	9,155,775
D. Del. Apr. 7, 2017	Synthon B.V.; Synthon Pharmaceuticals Inc.; Synthon s.r.o.; Pfizer Inc.	9,155,775
D. Del. May 24, 2017	Sandoz Inc.; Momenta Pharmaceuticals Inc.	9,155,775
D. Del. Jun. 7, 2017	Dr. Reddy's Laboratories Ltd.; Dr. Reddy's Laboratories Inc.	9,155,775
D. Del. Jul. 20, 2017	Amneal Pharmaceuticals LLC; Amneal Pharmaceuticals Co. GmbH	9,155,775

Nexavar
Sorafenib

Settled. Likely launch anytime - after Jan-2020 (API patent expiry).

In 2015, Bayer filed patent infringement lawsuits in a U.S. federal court against Mylan (Natco's partner). In October 2017, Bayer reached an agreement with Mylan to settle this patent dispute. Under the settlement terms, Mylan will obtain a license to sell its generic version of Nexavar in the US at a date after the expiration of the patent for the active ingredient expiring in January 2020. In 2016, Bayer had received another notice of ANDA IV application by Teva. Bayer filed a patent infringement lawsuit against Teva in the same U.S. federal court. In January 2018, Bayer reached an agreement with Teva to settle this patent dispute. Under the settlement terms, Teva will obtain a license to sell its generic version of Nexava in the United States at a date after the expiration of the patent for the active ingredient expiring in January 2020.

Figure-55: Nexavar / Sorafenib snapshot

Brand	Nexavar
API	Sorafenib
Innovator/Marketer	Bayer
Indication	Oncology / Cancer
Dosage Form	Tablets
Strengths (innovator)	200 mg (Daily 400 mg - 2 tablets, orally, twice daily)
Initial Innovator Approval	Dec-2005
Natco's Partner	Mylan
Filing	Para-IV FTF
Settlement	Yes. Settlement with Mylan : Oct-2017 Teva: Jan-2018
Natco/Teva generic launch	Any time after the API patent expiry (which is on 12-Jan-2020)
Patent Expiry in the US	API: 2020
US Sales, CY18	US Sales, 2018: USD 255 mn (declining trend for the last three years). Peak US Sales of USD 360 mn in CY15. Competitive pressure is expected to have an impact on sales performance going ahead. Nexavar is not very successful product (compared to US sales of other innovative oncology drugs).
Competitive landscape	Mylan, Teva (same terms of settlement)
DMFs	Total 13 DMFs Teva, Natco, Reliance Life, Cipla, Alembic, Hetero, MSN, Delmar Chemicals, Yabao Pharma, Chongqing Carelife
Generic companies involved in patent litigation	Mylan, Teva, Apotex

Figure-56: Bayer - Nexavar / Sorafenib US Sales

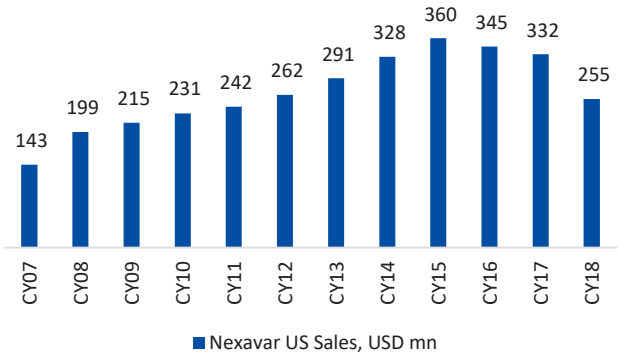


Figure-57: Bayer - Nexavar / Sorafenib US Sales

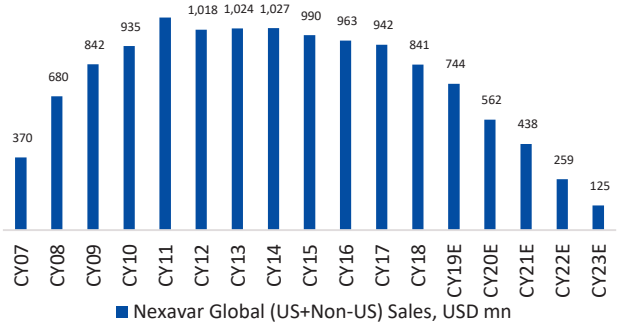


Figure-58: Sorafenib DMFs

Submit Date	Holder (Sorafenib)
3/10/2011	Natco Pharma Ltd
9/18/2012	Sichuan Xieli Pharmaceutical Co Ltd
12/21/2012	Natco Pharma Ltd
11/20/2013	Zhejiang Jiuzhou Pharmaceutical Co Ltd
9/23/2014	Reliance Life Sciences Pvt Ltd
6/30/2015	Yabao Pharmaceutical Group Co Ltd
11/29/2015	Alembic Pharmaceuticals Ltd
1/30/2016	MSN Laboratories Private Ltd
2/23/2016	Teva Pharmaceutical Industries Ltd
1/28/2016	Hetero Labs Ltd
12/20/2017	Delmar Chemicals Inc
3/30/2018	Cipla Ltd
7/9/2018	Chongqing Carelife Pharmaceutical Co Ltd
3/29/2019	MSN Laboratories Private Ltd
9/30/2019	Cipla Ltd
9/30/2019	Alembic Pharmaceuticals Ltd

Figure-59: Nexavar Patent Litigation

Submit Date	ANDA Filer	Lanthanum Carbonate Patent no.
D. Del. Jan. 30, 2015	Mylan Pharmaceuticals Inc.; Mylan Inc.	8,618,141; 8,877,933
D. Del. Dec. 17, 2015	Mylan Inc.; Mylan Pharmaceuticals Inc.	7,351,834; 7,235,576; 8,841,330; 8,877,933; 7,897,623
D. Del. Dec. 16, 2016	Teva Pharmaceutical Industries Ltd.; Teva Pharmaceuticals USA, Inc.	8,877,933
D. Del. Oct. 4, 2018	Apotex Inc.; Apotex Corp.	8,877,933; 9,737,488

Figure-60: Pharmaceuticals Patent Expiration in US

Patent	Year
Active ingredient	2020
Salt form	-
Polymorph	2027
Formulation	2028

Revlimid
lenalidomide

Case settled. Volume-limited launch in Mar-2022. Unlimited quantity from Jan 31, 2026. Patent expiry April-2027.

Although the agreed-upon percentages are confidential, they increase gradually each period to no more than a single-digit percentage in the final volume-limited period.

Settlement terms /details:
In settlement of all outstanding claims in the litigation, Celgene agreed to provide Alvogen with a license to Celgene's patents required to manufacture and sell certain volume-limited amounts of generic lenalidomide in the United States beginning on a confidential date that is some time after the March 2022 volume-limited license date that Celgene previously provided to Natco. The volume limit is expected to be a mid-single-digit percentage of the total Lenalidomide capsules dispensed in the United States during the first full year of entry.
The volume limitation is expected to increase gradually every 12 months until the March of 2025, and is not expected to exceed one-third of the total Lenalidomide capsules dispensed in the U.S. in the final year of the volume-limited license under this agreement.

Figure-61: Revlimid / Lenalidomide snapshot

Brand	Revlimid
API	Lenalidomide
Innovator/Marketer	Celgene
Indication	Oncology
Dosage Form	Capsules
Strengths (innovator)	2.5, 5, 10, 15, 20, 25 mg
Initial Innovator Approval	Dec-2005
Natco's Partner	Alvogen. Earlier partner was Arrow (owned by Teva now).
Natco's filing	Para-IV/FTF
Settlement	Yes
Natco/Alvogen generic launch	March-2022
Patent Expiry in the US	2027
Settlement timelines	
Jan-2019	Settlement with Alvogen
In Dec-2015	Settlement with Natco+Arrow (Teva), Natco's partner (then) - Arrow International Limited, a unit of Allergan Plc. Arrow is now owned by Teva
US Sales	CY18 USD 6.5 bn, CY21E: USD 8.6 bn
Competitive landscape	March-2022 launch by Alvogen (Natco) only
Generic companies involved in patent litigation:	Natco, Lotus (Alvogen), Arrow (Watson - Teva), ANDA Inc (Teva), Dr Reddys, Cadila HC, Cipla, Apotex, Sun Pharma, Hetero
DMFs	Total 12 DMFs Mylan, Sun Pharma, Dr Reddy's, Cipla, Reliance Lie, Hetero, MSN, Apicore US, Changzhou Pharma, FIS Fabbrica Italiana

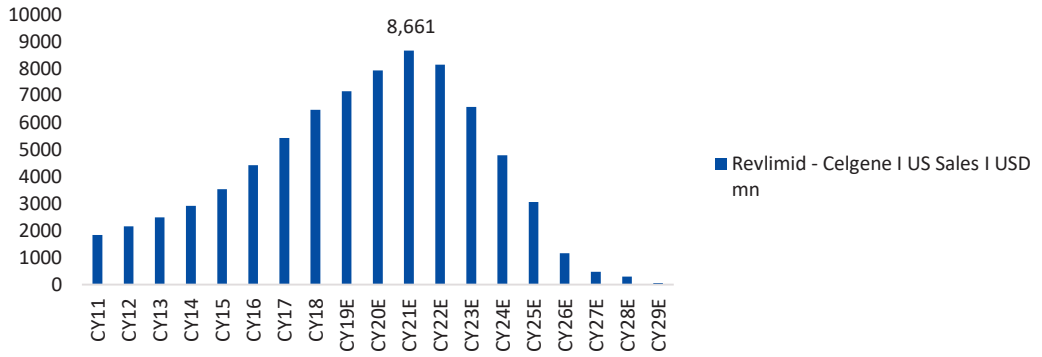
Figure-62: Lenalidomide DMFs

Submit Date	Holder (Lenalidomide)
12/29/2009	Mylan Laboratories Ltd
12/2/2010	Apicore Us Llc
6/4/2013	Fis Fabbrica Italiana Sintetici Spa
2/3/2014	Reliance Life Sciences Pvt Ltd
9/16/2016	Cipla Ltd
9/30/2015	Dr Reddys Laboratories Ltd
9/30/2015	Dr Reddys Laboratories Ltd
12/27/2017	Sun Pharmaceutical Industries Ltd
3/28/2017	Msn Laboratories Private Ltd
6/2/2017	Changzhou Pharmaceutical Factory
9/13/2017	Msn Laboratories Private Ltd
12/1/2017	Hetero Labs Ltd

Figure-63: Revlimid Patent Litigation

Date	ANDA Filer	Revlimid Patent no.
D.N.J. Oct. 8, 2010	Natco Pharma Ltd.	5,635,517; 6,045,501;6,281,230; 6,315,720;6,555,554; 6,561,976;6,561,977; 6,755,784;7,119,106; 7,465,800
D. N.J. July 20, 2012	Natco Pharma Limited; Arrow International Limited; Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.	5,635,517; 6,045,501; 6,281,230; 6,315,720; 6,555,554; 6,561,976; 6,561,977; 6,755,784; 7,119,106; 7,465,800; 7,189,740; 7,968,569; 7,977,357; 8,193,219
D.N.J. May 15, 2014	Natco Pharma Ltd.; Arrow International Ltd.; Actavis Inc.; Watson Laboratories Inc.; Watson Pharma Inc.; Anda Inc.	8,530,498; 8,626,531; 8,648,095
D.N.J. Oct. 20, 2016	Dr. Reddy's Laboratories, Ltd.; Dr. Reddy's Laboratories, Inc.	7,855,217; 7,968,569; 8,530,498; 8,648,095; 9,101,621; 9,101,622
D.N.J. Apr. 12, 2017	Zydus Pharmaceuticals (USA) Inc.; Zydus International Pvt. Ltd.; Cadila Healthcare Ltd.	7,465,800; 7,855,217; 7,968,569; 8,530,498; 8,648,095; 9,101,621; 9,101,622
D.N.J. Jul. 20, 2017	Dr. Reddy's Laboratories, Ltd.; Dr. Reddy's Laboratories, Inc.	7,189,740; 8,404,717; 9,056,120
D.N.J. Aug. 15, 2017	Cipla Ltd.	7,465,800; 7,855,217; 7,968,569; 8,530,498; 8,648,095; 9,101,621; 9,101,622
D.N.J. Sept. 6, 2017	Lotus Pharmaceutical Co. Ltd.; Alvogen Pine Brook LLC	5,635,517; 6,315,720; 6,561,977; 6,755,784; 7,189,740; 7,465,800; 7,855,217; 7,968,569; 8,315,886; 8,404,717; 8,530,498; 8,626,531; 8,648,095; 9,056,120; 9,101,621; 9,101,622
D.N.J. Jan. 11, 2018	Apotex Inc.	6,315,720; 6,561,977; 6,755,784; 7,465,800; 7,468,363; 7,855,217; 8,315,886; 8,626,531; 8,741,929
D.N.J. Apr. 27, 2018	Zydus Pharmaceuticals (USA) Inc.; Cadila Healthcare Ltd.	7,977,357; 8,193,219; 8,431,598
D.N.J. Apr. 12, 2018	Dr. Reddy's Laboratories, Ltd.; Dr. Reddy's Laboratories, Inc.	6,315,720; 6,561,977; 6,755,784; 8,315,886; 8,626,531
D.N.J. May 8, 2018	Cipla Ltd.	7,977,357; 8,193,219; 8,431,598
D.N.J. Jul. 13, 2018	Sun Pharma Global FZE; Sun Pharma Global Inc.; Sun Pharmaceutical Industries Inc.; Sun Pharmaceutical Industries Ltd.	7,465,800; 7,855,217; 7,968,569
D.N.J. Jul. 10, 2018	Lotus Pharmaceutical Co., Ltd.; Alvogen Pine Brook LLC	7,977,357; 8,193,219; 8,431,598
D.N.J. Feb. 26, 2019	Apotex Inc.	7,189,740; 8,404,717;9,056,120
D.N.J. Dec. 20, 2018	Hetero Labs Ltd.; Hetero Labs Limited Unit-V; Hetero Drugs Ltd.; Hetero USA Inc.	7,465,800; 7,468,363; 7,855,217; 8,741,929
D.N.J. July 3, 2019	Cipla Ltd.	U.S. Patent Nos. 7,189,740; 7,465,800; 7,855,217; 7,968,569; 8,404,717; 8,530,498; 8,648,095; 9,056,120; 9,101,621; 9,101,622
D.N.J. Apr. 16, 2019	Sun Pharma Global FZE; Sun Pharma Global Inc.; Sun Pharmaceutical Industries, Inc.; Sun Pharmaceutical Industries Ltd.	U.S. Patent Nos. 7,977,357; 8,193,219; 8,431,598

Figure-64: Revlimid / Lenalidomide US Sales for Celgene, USD mn. CY21 peak



Kyprolis
carfilzomib

Natco settled in May-2019. Launch in 2027. Three strengths, sole FTF for one of the strengths (10mg).

Street expectation, in-line with settlement timeline; show sales decline in CY28. Size: USD 580 mn in US in 2018. USD 1bn in CY26. It's possible that Amgen (innovator) settled with other generic players (Apotex, Fresenius Kabi, Sagent Pharma).

Figure-65: Kyprolis/ Carfilzomib snapshot

Brand	Kyprolis
API	Carfilzomib
Innovator/Marketer	Amgen (Onyx Pharma)
Indication	Multiple Myeloma (cancer)
Dosage Form	Powder for Injection
Strengths (innovator)	10 mg, 30 mg or 60 mg, lyophilized powder in single-dose vial for reconstitution
Initial Innovator Approval US	July-2012
Natco's Partner	Breckenridge
Filing	Para-IV/FTF
Settlement	Yes. Settled in May-2019. Settlement for multiple strengths 10mg, 30mg, 60mg. Sole FTF for 10mg It's possible that Amgen also settled with Apotex, Fresenius Kabi, Sagent Pharma.
Natco/Breckenridge generic launch	Launch in 2027 or earlier in certain circumstances. Compositions and compounds patent expiry in the US: Dec-2017. Consensus numbers declining YoY in CY28.
Patent Expiry in the US	Compositions and compounds patent expiry in the US: Dec-2017.
US Sales, CY18	Size: USD 580 mn in US in 2018. USD 1bn in CY26. Consensus estimates showing YoY decline from 2028.
Competitive landscape	20mg, 60mg multiple players, Natco - sole in 10mg
DMFs	Total 9 DMFs Teva, Dr Reddy's, Laurus, MSN, Fresenius Kabi, Biophore India, Qilu Pharma, Chunghwa Chemical, Polymed Therapeutic
Para-IVs	Cipla, Dr Reddy's, Fresenius Kabi, Sagent Pharma, MSN Labs, Teva, Apotex, Aurobindo, Qilu Pharma, Breckenridge (Natco), InnoPharma
Generic companies involved in patent litigations:	Breckenridge Pharma, Sagent Pharms, MSN, Cipla, Apotex, InnoPharma, Dr Reddy's, Cadila HC, Teva, Quila, Apotex, Dr Reddy's, Aurobindo Pharma,

Figure-66: Kyprolis patent expiries

Patent	Geography	Timeline
Compositions and compounds	U.S	Dec-27
Methods of treatment	U.S	Apr-25
Methods of making	U.S	May-33

Figure-67: Amgen - Kyprolis US Sales, USD mn

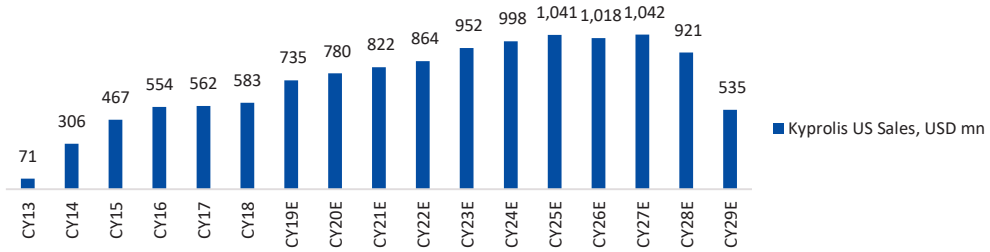


Figure-68: Carfilzomib DMFs

Submit Date	Holder (Carfilzomib)
8/29/2015	MSN Laboratories Private Ltd
1/30/2016	Fresenius Kabi Oncology Ltd
9/28/2015	Qilu Pharmaceutical Co Ltd
3/22/2016	Laurus Labs Ltd
1/21/2016	Teva Pharmaceutical Industries Ltd
12/29/2015	Chongqing Pharmaceutical Research Institute Co Ltd
2/26/2016	Polymed Therapeutics Inc
3/29/2016	Dr Reddys Laboratories Ltd
12/30/2016	Chunghwa Chemical Synthesis And Biotech Co Ltd
12/30/2017	Biophore India Pharmaceuticals Pvt Ltd

Figure-69: Kyprolis Patent Litigation

Date	ANDA Filer	Kyprolis Patent no.
D. Del. Oct. 27, 2016	Breckenridge Pharmaceutical Inc.	7,232,818; 7,417,042; 7,491,704; 7,737,112; 8,129,346; 8,207,125; 8,207,126; 8,207,127; 8,207,297
D. Del. Oct. 26, 2016	Sagent Pharms., Inc.	7,232,818; 7,417,042; 7,491,704; 7,737,112; 8,129,346; 8,207,125; 8,207,126; 8,207,127; 8,207,297
D. Del. Oct. 26, 2016	MSN Laboratories Private Ltd; MSN Pharmaceuticals, Inc.	7,737,112
D. Del. Oct. 24, 2016	CIPLA Ltd.; CIPLA USA, Inc.	7,232,818; 7,417,042; 7,491,704; 7,737,112; 8,129,346; 8,207,125; 8,207,126; 8,207,127; 8,207,297
D. Del. Nov. 8, 2016	Apotex Inc.; Apotex Corp.	7,417,042; 7,737,112; 8,207,297
D. Del. Nov. 8, 2016	InnoPharma Inc.	7,417,042; 7,737,112; 8,207,297
D. Del. Nov. 4, 2016	Dr. Reddy's Laboratories, Inc.; Dr. Reddy's Laboratories, Ltd.	5,908,838; 7,790,705; 7,919,483; 8,252,776; 8,268,804; 8,722,650
D. Nev. Nov. 4, 2016	Dr. Reddy's Laboratories, Inc.; Dr. Reddy's Laboratories, Ltd.	8,293,728; 8,318,715; 8,357,677; 8,367,652; 8,377,920; 8,399,446; 8,415,335; 8,426,399; 8,431,560; 8,440,650; 8,518,929; 8,524,698; 8,546,372; 8,617,594
D. Del. Nov. 3, 2016	Cadila Healthcare Ltd.; Teva Pharmaceuticals USA, Inc.; Zydus Worldwide DMCC	6,884,434; 8,246,979; 8,246,980; 8,617,591
D. Del. Nov. 1, 2016	Qilu Pharma, Inc.; Qilu Pharmaceutical Co., Ltd.	7,737,112
D. Del. Nov. 1, 2016	Dr. Reddy's Laboratories, Inc.; Dr. Reddy's Laboratories, Ltd.	7,737,112
D. Del. Apr. 20, 2017	Teva Pharmaceutical Industries Ltd.; Teva Pharmaceuticals USA, Inc.	7,232,818; 7,417,042; 7,491,704; 7,737,112; 8,129,346; 8,207,125; 8,207,126; 8,207,127; 8,207,297
D. Del. Aug. 30, 2017	Qilu Pharma, Inc.; Qilu Pharmaceutical Co., Ltd.	7,232,818; 7,417,042; 7,491,704; 8,129,346; 8,207,125; 8,207,126; 8,207,127; 8,207,297
D. Del. Aug. 24, 2017	Apotex Inc.; Apotex Corp.	7,232,818; 7,417,042; 7,491,704; 8,129,346; 8,207,125; 8,207,126; 8,207,127; 8,207,297
D. Del. Aug. 17, 2017	InnoPharma Inc.	7,232,818; 7,491,704; 8,129,346; 8,207,125; 8,207,126; 8,207,127
D. Del. Nov. 22, 2017	Aurobindo Pharma USA, Inc.	7,232,818; 7,417,042; 7,491,704; 7,737,112; 8,129,346; 8,207,125; 8,207,126; 8,207,127; 8,207,297
D. Del. Dec. 20, 2017	MSN Pharmaceuticals, Inc.; MSN Laboratories Private Ltd.	7,737,112
D. Del. Dec. 18, 2017	Dr. Reddys Laboratories, Inc.; Dr. Reddys Laboratories, Ltd.	7,232,818; 7,417,042; 7,491,704; 8,129,346; 8,207,125; 8,207,126; 8,207,127; 8,207,297
D. Del. Jan. 24, 2018	Apotex Inc.; Apotex Corp.	7,232,818; 7,417,042; 7,491,704; 7,737,112; 8,129,346; 8,207,125; 8,207,126; 8,207,127; 8,207,297
D. Del. Feb. 15, 2018	Breckenridge Pharmaceutical, Inc.	7,232,818; 7,417,042; 7,491,704; 7,737,112; 8,129,346; 8,207,125; 8,207,126; 8,207,127; 8,207,297
D. Del. Apr. 20, 2018	CIPLA Ltd.; CIPLA USA, Inc.	7,417,042; 7,737,112; 8,207,125; 8,207,126; 8,207,127
D. Del. Jan. 11, 2019	Breckenridge Pharmaceutical, Inc.	7,417,042; 7,737,112; 8,207,125

Treanda
bendamustine

Settled earlier, USFDA guidelines on another drug with the same API would mean launch pushed from earlier expectation of Nov-2019 to Dec-2022.

Bendamustine has three brands – Treanda, Bendeka and Belrapzo. Bendeka is a low-volume and short-time infusion (10 minutes) version of Treanda.

Natco has a Para-IV FTF on Treanda. As per the earlier settlement between Natco/Breckenridge and Cephalon (Teva), the launch was expected by 01-Nov-2019 or earlier in some circumstances. It was expected to be a shared exclusivity. But in Feb-2019, USFDA came out with an order related to Bendeka around orphan exclusivity. This has mostly pushed the earlier expected launch of Nov-2019 to Dec-2022.

Details of the USFDA Order: FDA has decided that generics to Treanda are subject to Bendeka's orphan exclusivity, and therefore (1) pending ANDAs will not receive final approval until December 7, 2022 (when Bendeka's orphan exclusivity expires), and (2) ANDAs that were approved after December 7, 2015 (the date of Bendeka's approval) will be converted to tentative approval until expiry of the exclusivity.

Figure-70: Bendamustine brands

Brand	Treanda	Bendeka	Belrapzo
API	Bendamustine HCl	Bendamustine HCl	Bendamustine HCl
Innovator / Marketer	Teva (Cephalon)	Teva (licensed from Eagle Pharma)	Eagle Pharma
Indication	Oncology / cancer	Oncology / cancer	Oncology / cancer
Dosage Form	solution for injection, powder for injection	solution for injection, powder for injection	Intravenous injection
Strengths (innovator)	Injection: solution 45 mg/0.5 mL or 180 mg/2 mL in a single-dose vial. Powder For Injection: 25 mg or 100 mg lyophilized powder in a single-dose vial for reconstitution.	Injection: 100 mg/4 mL (25 mg/mL) as a clear and colorless to yellow ready-to-dilute solution in a multiple-dose vial.	CLL: 100 mg/m^2 infused intravenously over 30 minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles. NHL: 120 mg/m^2 infused intravenously over 60 minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles.

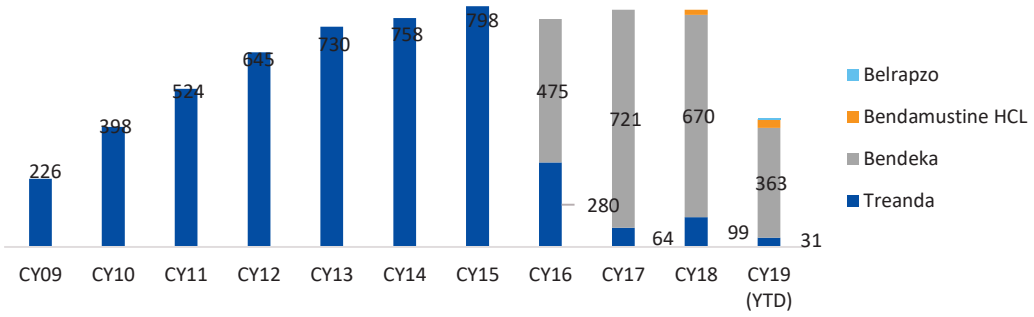
Figure-71: Treanda/Bendamustine snapshot

Brand	Treanda
API	Bendamustine
Innovator/Marketer	Cephalon (Teva)
Indication	Cancer
Dosage Form	Injection, powder for injection
Strengths (innovator)	Injection: solution 45 mg/0.5 mL or 180 mg/2 mL in a single-dose vial. Powder For Injection: 25 mg or 100 mg lyophilized powder in a single-dose vial for reconstitution.
Initial Innovator Approval	Mar-2008
Natco's partner	Breckenridge Pharma
Filing	Para-IV FTF / Shared exclusivity with other players
Filing date/month	
Settlement	It was a settled opportunity. But now, there is incremental development. Hence, the earlier terms may not remain valid.
Natco's generic launch	earlier settlement : 01-Nov-2019 or earlier in some circumstances
Settlement timelines	
US Sales, CY 2018, USD mn	US Sales, CY18, USD 642mn
	Natco had received final ANDA approval in Jan-2017
Competitive landscape	Multiple players
	Treanda: Actavis, Apotex, Dr Reddy's, Eagle, Glenmark, InnoPharma, Panacea, Sagent Agila, Sandoz, Sun Pharma, Nang Kuang, Pharmascience, Uman, Wockhardt, Accord (Intas), Breckenridge, Emcure, Eurohealth, Hospira Inc
Para-IVs	Bendeka: Apotex, Fresenius Kabi
Generic companies involved in patent litigations:	Treanda: Accord (Intas), Actavis (Teva), Agila Specialties, Apotex, Breckenridge Pharma (Natco), Breckenridge Pharma, Canda NK-1, Dr Reddy's, Eagle Pharma, Emcure, Fresenius Kabi, Glenmark, Hetero, Hikma - West-Ward Pharma, Hikma - Ben Venue Labs, Hikma, Hospira (Pfizer), InnoPharma, Intas, Nang Kuang Pharma, Natco, Onco Therapies, Panacea Biotec, Pharmascience Inc, Sagent Pharma, Sandoz, Sun Pharma, Uman Pharma, USA Eurohealth International SARL, Wockhardt
	Bendeka: Apotex, Fresenius Kabi, Hospira, Mylan, Slayback Pharma
DMFs	Total 22 DMFs Natco, Dr Reddys, Hetero, Shilpa, Emcure, Sun Pharma, MSN, Biophore India, Fresenius Kabi, ChemPacific Corp, Olan Spa, Wisdom, Heraeus Deutschland Gmbh, Laborchemie Apolda Gmbh, Nerpharma Srl, Navinta Llc, Chongqing Huapont, Lianyungang Runzhong, Fuxin Long Rui Pharm

Figure-72: Bendamustine DMFs

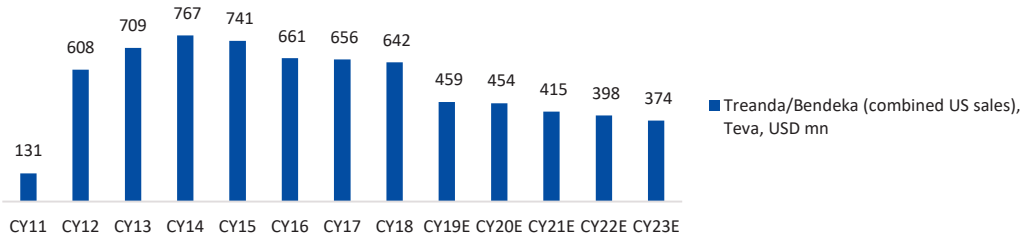
Submit Date	Holder (Bendamustine)
3/13/2009	Chempacific Corp
3/30/2011	Dr Reddys Laboratories Ltd
11/8/2011	Shilpa Medicare Ltd
11/18/2011	Heraeus Deutschland Gmbh And Co Kg
11/24/2011	Chongqing Huapont Pharmaceutical Co Ltd
2/21/2012	Hetero Labs Ltd
3/31/2012	Emcure Pharmaceuticals Ltd
2/24/2012	Olon Spa
6/8/2012	Nerpharma Srl
12/21/2012	Fresenius Kabi Oncology Ltd
12/18/2012	Natco Pharma Ltd
2/24/2014	Laborchemie Apolda Gmbh
1/4/2013	Sun Pharmaceutical Industries Ltd
9/18/2013	Lianyungang Runzhong Pharmaceutical Co Ltd
6/15/2013	Msn Laboratories Private Ltd
9/19/2013	Navinta Llc
9/20/2013	Biophore India Pharmaceuticals Pvt Ltd
3/28/2014	Wisdom Pharmaceutical Co Ltd
7/29/2014	Itf Chemical Ltda
7/27/2014	Beijing Huikang Boyuan Chemical Tech Co Ltd
2/11/2015	Chongqing Huapont Pharmaceutical Co Ltd
12/18/2018	Fuxin Long Rui Pharmaceutical Co Ltd

Figure-73: Sales of various Bendamustine brands in US, USD mn, BB



Belrapzo: Eagle Pharma, bendamustine hydrochloride injection, 100 mg/ 4mL, a Ready-to-Dilute (RTD) solution for your CLL and NHL patients (oncology). Approve 2008.

Figure-74: Teva - Treanda, Bendeka combined sales in US



For Teva, Bendeka and Treanda , the combined revenues in North America were under pressure in 2019 mainly due to lower volumes and lower pricing, resulting partly from the June 2018 launch of a ready-to-dilute bendamustine hydrochloride by Eagle Pharmaceuticals. Separately, Teva has a licensing agreement with Eagle Pharma related to the API.

Figure-75: Treanda Patent Litigation

Date	ANDA Filer (Treanda)	Treanda Patent no.
D. Del. Oct. 21, 2013	Eagle Pharmaceuticals, Inc.	8,445,524
D. Del. Dec. 31, 2013	Sandoz Inc.	8,445,524; 8,436,190
D. Del. Dec. 26, 2013	Glenmark Pharmaceuticals Ltd.; Glenmark Generics Ltd.; Glenmark Generics S.A.; Glenmark Generics Inc. USA	8,445,524
D. Del. Dec. 26, 2013	Hospira Inc.	8,445,524; 8,436,190
D. Del. Dec. 26, 2013	Accord Healthcare Inc.; Intas Pharmaceuticals Ltd.	8,445,524; 8,436,190
D. Del. Dec. 26, 2013	Sun Pharma Global FZE; Sun Pharmaceutical Industries Ltd.; Sun Pharmaceutical Industries Inc.	8,445,524; 8,436,190
D. Del. Dec. 20, 2013	InnoPharma Inc.	8,445,524; 8,436,190
D. Del. Dec. 20, 2013	Dr. Reddy's Laboratories Ltd.; Dr. Reddy's Laboratories Inc.	8,445,524; 8,436,190
D. Del. Dec. 19, 2013	Hetero Labs Ltd.; Hetero USA Inc.	8,445,524
D. Del. Jan. 31, 2014	Actavis LLC; Actavis Elizabeth LLC	8,445,524; 8,436,190
D. Del. Mar. 14, 2014	Emcure Pharmaceuticals Ltd.; Emcure Pharmaceuticals USA Inc.	8,445,524
D. Del. Mar. 14, 2014	Dr. Reddy's Laboratories Ltd.; Dr. Reddy's Laboratories Inc.	8,609,863
D. Del. Mar. 14, 2014	Sun Pharma Global FZE; Sun Pharmaceutical Industries Ltd.; Sun Pharmaceutical Industries Inc.	8,609,863
D. Del. Apr. 30, 2014	Uman Pharma Inc.	8,436,190; 8,445,524
D. Del. May 27, 2014	Breckenridge Pharmaceutical Inc.; Natco Pharma Ltd.	8,436,190; 8,445,524; 8,609,863
D. Del. May 9, 2014	InnoPharma Inc.	8,609,863
D. Del. Aug. 13, 2014	Ben Venue Laboratories Inc.; Hikma Pharmaceuticals PLC; West-Ward Pharmaceutical Corp.	8,436,190; 8,445,524; 8,609,863; 8,791,270
D. Del. Aug. 12, 2014	Eagle Pharmaceuticals Inc.	8,791,270
D. Del. Sept. 26, 2014	Sun Pharma Global FZE; Sun Pharmaceutical Industries Ltd.	8,791,270
D. Del. Sept. 26, 2014	Hospira Inc.	8,791,270
D. Del. Sept. 26, 2014	Dr. Reddy's Laboratories Ltd.; Dr. Reddy's Laboratories Inc.	8,791,270
D. Del. Sept. 25, 2014	Sandoz Inc.	8,791,270
D. Del. Sept. 25, 2014	InnoPharma Inc.	8,791,270
D. Del. Sept. 25, 2014	Agila Specialties Inc.; Onco Therapies Ltd.	8,791,270
D. Del. Sept. 2, 2014	Nang Kuang Pharmaceutical Co.; Canda NK-1 LLC	8,436,190; 8,445,524; 8,609,863; 8,791,270
D. Del. Sept. 2, 2014	Sagent Pharmaceuticals Inc.; Sagent Agila LLC	8,436,190; 8,445,524; 8,609,863; 8,791,270
D. Del. Oct. 21, 2014	Wockhardt Bio Ltd.; Wockhardt Ltd.; Wockhardt USA LLC	8,445,524; 8,436,190; 8,609,863; 8,791,270
D. Del. Feb. 23, 2015	Dr. Reddy's Laboratories Ltd.; Emcure Pharmaceuticals Ltd.; Emcure Pharmaceuticals USA Inc.; Pharmascience Inc.; Hospira Inc.; Breckenridge Pharmaceutical Inc.; Natco Pharma Ltd.; Hetero Labs Ltd.; Hetero USA Inc.; Sun Pharmaceutical Industries Ltd.; Actavis LLC; Sagent Pharmaceuticals Inc.; Wockhardt Bio AG; Wockhardt Ltd.; Wockhardt USA LLC; Sun Pharma Global FZE	8,669,279; 8,883,836; 8,895,756
D. Del. Feb. 23, 2015	Sandoz Inc.; Accord Healthcare Inc.; Intas Pharmaceuticals Ltd.; InnoPharma Inc.; Agila Specialties Inc.; Onco Therapies Ltd.; Glenmark Pharmaceuticals Ltd.; Glenmark Generics SA; USA Eurohealth International SARL; West-Ward Pharmaceutical Corp.; Glenmark Generics Ltd.; Glenmark Generics Inc. USA	8,669,279; 8,883,836; 8,895,756
D. Del. May 19, 2015	Apotex Inc.; Apotex Corp.	8,436,190; 8,445,524; 8,609,863; 8,669,279; 8,791,270; 8,883,836; 8,895,756
D. Del. June 24, 2015	Fresenius Kabi USA LLC	8,344,006
D. Del. Aug. 25, 2015	Panacea Biotec Ltd.	8,883,836; 8,669,279; 8,895,756; 8,445,524; 8,791,270

Figure-76: Bendeka Patent Litigation

Date	ANDA Filer (Bendeka)	Bendeka Patent no.
D. Del. Aug. 24, 2017	Fresenius Kabi USA, LLC	8,609,707; 8,791,270; 9,000,021; 9,034,908; 9,144,568; 9,265,831; 9,572,796; 9,572,797; 9,572,887; 9,579,384; 9,597,397; 9,597,398; 9,597,399
D. Del. Aug. 18, 2017	Apotex Inc.; Apotex Corp.	8,609,707; 8,791,270; 9,000,021; 9,034,908; 9,144,568; 9,265,831; 9,572,796; 9,572,797; 9,572,887; 9,579,384; 9,597,397; 9,597,398; 9,597,399
D. Del. Aug. 16, 2017	Slayback Pharma LLC	8,791,270
D. Del. Dec. 12, 2017	Mylan Laboratories Ltd.	8,609,707; 8,791,270; 9,000,021; 9,034,908; 9,144,568; 9,265,831; 9,572,796; 9,572,797; 9,572,887; 9,579,384; 9,597,397; 9,597,398; 9,597,399
D. Del. Jan. 19, 2018	Slayback Pharma LLC	9,572,887
D. Del. Jul. 19, 2018	Hospira, Inc.	9,000,021; 9,034,908; 9,144,568; 9,572,887; 9,579,384; 9,597,397; 9,597,398; 9,597,399; 10,010,533
D. Del. Sept. 20, 2018	Slayback Pharma LLC	8,609,707; 9,265,831; 9,572,796; 9,572,797; 10,010,533
D. Del. Oct. 15, 2018	Fresenius Kabi USA, LLC; Mylan Laboratories Ltd.	10,010,533; 10,052,385

Zotress, Afinitor
Everolimus

Zortress – Under litigation.
Afinitor – No clarity yet. Launch in the near future is a likely scenario. Two generic players with strengths other than that of Natco's filing are in the market now.

Of the four available strengths (2.5, 5, 7.5 and 10mg), Natco's filing is on 10mg. In Dec-2019, Teva and Endo received ANDA approvals for 2.5, 5, 7.5 mg. Endo launched the product, we assume that Teva would have launched the drug or would be in the market soon.

No ANDA approval for 10mg. Subject to litigation / settlement issues and ANDA approval, Natco's partner – Breckenridge could launch the drug in the near future.

Afinitor Disperz is available as 2 mg, 3 mg, and 5 mg tablets. Total market size for all the strengths of Afinitor is USD 410 mn (IQVIA). Disperz is a small market.

Novartis has two Everolimus brands in US. Zortress: transplantation / immunosuppressant. Afinitor: oncology. Natco's Para-IV/ FTF. Para-IV / FTF - on 10mg strength of Afinitor and on Zortress.

Novartis had earlier indicated that it had resolved patent litigation with certain generic manufacturers which may result in limited generic competition for Afinitor towards the end of 2019. It also resolved patent litigation relating to Afinitor Disperz. Novartis did not disclose names of generic companies with which it had resolved patent disputes. Patent resolution with Natco-Breckenridge is a likely scenario.

Teva and Endo Pharma (through Par Pharma) received ANDA approvals. On December 10, 2019, Endo launched generic tables (2.5 mg, 5 mg and 7 mg).

No clarity of Zortress litigation.

Zortress is a more potent version of Afinitor. All the strengths are 1/10th of that of Afinitor and are less than 1mg strength. Hence, for now, it would be worth watching how the generic availability of Afinitor impacts Zortress sales. But a complete replacement seems to be a less likely scenario.

Figure-77: Afinitor, Zortress / Everolimus snapshot

Brand	Afinitor	Zortress
API	Everolimus	Everolimus
Indication	Oncology / cancer	Transplantation / immunosuppressant
Innovator / Marketer	Novartis	Novartis
Natco's partner	Breckenridge Pharma	Breckenridge Pharma
Initial USFDA Approval for the innovator	Mar-2009	Apri-2010
US Sales, CY 2018, USD mn	USD 930 mn	USD 145 mn
Filing type	Para-IV / FTF on 10 mg	Para-IV / FTF
Dosage Form	Tablet Dispersible tablet for oral suspension	Tablet
Strengths	most of the approved indications are under 10mg strength (some indications are under 4.5 mg/m2 and 5.0 mg/m2	0.25mg, 0.5mg, and 0.75mg
Natco's filing	10 mg	0.25mg, 0.5mg, and 0.75mg
Natco's filing date/month	Sept-2014	Sept-2014
Generic	There is currently no generic competition in the US	There is currently no generic competition in the US
DMFs	Total 13 DMFs Natco, Biocon, Concord Biotech, Apotex, Hangzhou Huadong Medicine Group, Chunghwa Chemical Synthesis, Chengdu Yacht Bio, Scinopharm Taiwan, Brightgene Biomedical	Same API. Same DMFs.
Generic companies involved in patent litigation	Breckenridge (Natco), Roxane Labs and Boehringer Ingelheim Roxane Inc (Roxane and BI Roxane are Hikma companies), Teva, Mylan, Par (Endo).	Breckenridge (Natco), Roxane Labs and Boehringer Ingelheim Roxane Inc (Roxane and BI Roxane are Hikma companies)
Patenr resolution / settlement	In the US, Novartis has resolved patent litigation with certain generic manufacturers which may result in limited generic competition for Afinitor toward the end of 2019, and has resolved patent litigation relating to Afinitor Disperz.	No settlement

Figure-78: Patent expiries: Afinitor: Several patent expiries in 2019

Pediatric Exclusivity (PE), Patent Term Extension (PTE), Patent Term Adjustment (PTA)

US: Patent on compound (2014), PTE (2019), PE (2020); patent on dispersible tablet formulation (2022), PE (2023); patent on antioxidant (2019); patent on antioxidant (2019), PE (2020); patent on tuberous sclerosis complex (TSC)/subependymal giant cell astrocytoma (SEGA) use (2022), PE (2022); patent on breast cancer use (2022), PE (2022); patent on renal cell carcinoma use (2025), PE (2026); patent on pancreatic neuroendocrine tumor use (2028); RDP for neuroendocrine tumors of gastrointestinal or lung origin (2019), PE (2019); ODE for TSC/renal angiomyolipoma (2019), PE (2019).

Figure-79: Patent expiries: Zotress

US: Patent on compound (2014), PTE (2019), PE (2020); patent on dispersible tablet formulation (2022), PE (2023); patent on antioxidant (2019); patent on antioxidant (2019), PE (2020).

Figure-80: Everolimus DMFs

Submit Date	Holder (Everolimus)
6/14/2013	Concord Biotech Ltd
12/17/2012	Hangzhou Huadong Medicine Group Kangrun Pharmaceutical Co Ltd
2/8/2013	Chunghwa Chemical Synthesis And Biotech Co Ltd
7/1/2013	Chunghwa Chemical Synthesis And Biotech Co Ltd
6/5/2015	Chengdu Yacht Bio-Technology Co Ltd
9/30/2015	Biocon Ltd
9/30/2015	Biocon Ltd
9/30/2015	Natco Pharma Ltd
10/19/2015	Scinopharm Taiwan Ltd
10/27/2016	Apotex Fermentation Inc
5/2/2018	Biocon Ltd
9/20/2017	Brightgene Biomedical Technology Co Ltd
8/28/2019	CKD Bio Corp

Figure-81: Afinitor Patent Litigation

Date	ANDA Filer	Afinitor Everolimus Patent no.
D. Del. Dec. 23, 2014	Roxane Laboratories Inc.	5,665,772; 7,297,703; 7,741,338
D. Del. Dec. 18, 2014	Par Pharmaceutical Inc.	5,665,772; 7,297,703; 7,741,338
D. Del. Jan. 23, 2015	Par Pharmaceutical Inc.	5,665,772; 7,297,703; 7,741,338
D. Del. June 10, 2015	Par Pharmaceutical Inc.	9,006,224
D. Del. June 10, 2015	Roxane Laboratories Inc.	8,410,131; 9,006,224
D. Del. Nov. 13, 2015	Par Pharmaceutical Inc.	8,436,010
D. Del. June 13, 2016	Breckenridge Pharmaceutical Inc.	5,665,772; 8,410,131; 8,778,962
D. Del. Apr. 13, 2017	Breckenridge Pharmaceutical, Inc.	5,665,772; 8,410,131; 8,778,962
D. Del. Apr. 7, 2017	Teva Pharmaceuticals USA, Inc.	8,410,131; 8,436,010; 8,778,962; 9,006,224
D. Del. Jun. 30, 2017	Teva Pharmaceuticals USA, Inc.	5,665,772
D. Del. June 5, 2019	Mylan Pharmaceuticals Inc.	U.S. Patent Nos. 5,665,772; 8,436,010; 8,778,962;

Figure-82: Zortress Patent Litigation

Date	ANDA Filer	Zortress Everolimus Patent no.
S.D. Fla. Aug. 15, 2014	Breckenridge Pharmaceutical Inc.	5,665,772; 6,004,973; 6,239,124; 6,455,518
D. Del. Aug. 13, 2014	Breckenridge Pharmaceutical Inc.	5,665,772; 6,004,973; 6,239,124; 6,455,518
S.D. Ohio Sept. 17, 2014	Roxane Laboratories Inc.; Boehringer Ingelheim Roxane Inc.	5,665,772; 6,004,973; 6,239,124; 6,455,518
D. Del. Sept. 16, 2014	Roxane Laboratories Inc.; Boehringer Ingelheim Roxane Inc.	5,665,772; 6,004,973; 6,239,124; 6,455,518

Figure-83: Afinitor Disperz Patent Litigation

Date	ANDA Filer	Afinitor Disperz Everolimus Patent no.
N.D. W.Va. Apr. 10, 2017	Mylan Pharmaceuticals Inc.	5,665,772; 8,617,598; 8,778,962
D. Del. Apr. 7, 2017	Mylan Pharmaceuticals Inc.	5,665,772; 8,617,598; 8,778,962

Figure-84: Afinitor US Sales, Novartis, USD mn, BB

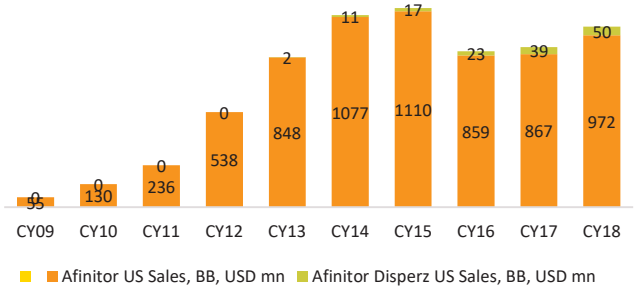
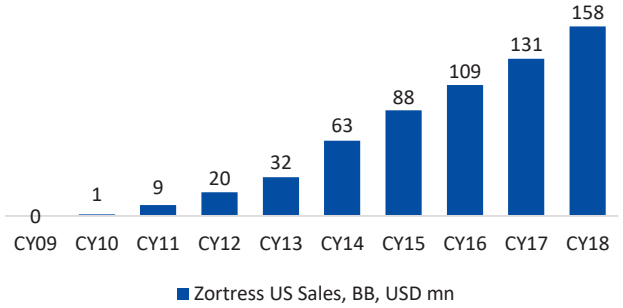


Figure-85: Zortress US Sales, Novartis



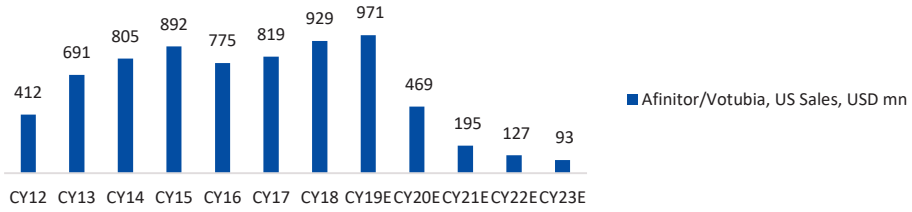
Novartis disclose combined sales for separate brands of everolimus.
Afinitor: oncology, Votubia: non-oncology (benign/non-cancerous tumours caused by the genetic disease tuberous sclerosis).

Figure-86: US Sales

USD mn	CY17	CY18
Afinitor/Votubia	819	929
Zortress/Certican	129	145

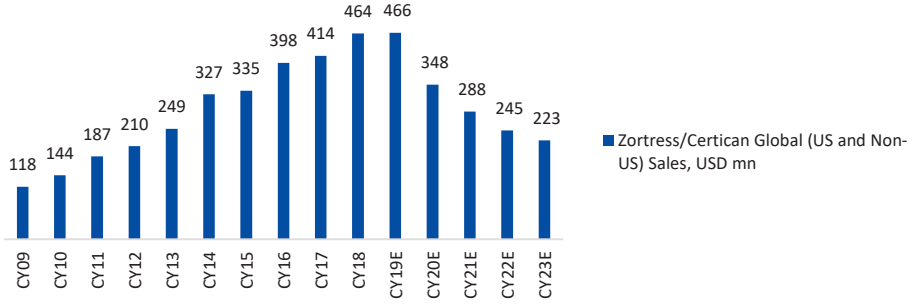
Estimates are available for the combination. Significant erosion in CY20E.

Figure-87: Afinitor/Votubia US Sales



For Zotress, estimates are available for the combination: Zotress/Certican. For the Global market. Cetrican: API: everolimus. Indication: prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogeneic renal or cardiac transplant. In kidney and heart transplantation, Certican is used in combination with ciclosporin for microemulsion and corticosteroids.

Figure-88: Zortress/Certican Global (US and Non-US) Sales



Aubagio
teriflunomide

Appears to be an extremely competitive opportunity.
Sanofi settled with 20 companies. All the 20 companies will launch the version on March 12, 2023. Therefore, for Natco - it may not be an interesting opportunity.

Sanofi has not disclosed specific names of generic players (including Natco/Alvogen). We assume that Natco/Alvogen is part of the deal.

Figure-89: Aubagio / Teriflunomide snapshot

Brand	Aubagio
API	Teriflunomide
Innovator / Marketer	Sanofi
Indication	Multiple Sclerosis
Dosage Form	Tablets
Strengths (innovator)	7mg, 14mg
Initial Innovator Approval US	Sept-2012
Natco's partner	Alvogen
Filing	Para-IV
Settlement	Yes. Settled. Sanofi settled with 20 companies. All the 20 companies will launch the drug on March 12, 2023
Natco's generic launch	Mar-2023
US Sales	CY2018 USD 1367 mn Consensus US Sales - 2023 is the first year of decline, indicating generic launches.
Competitive landscape	Likely to be extremely competitive, 20 players
DMFs	Total 19 DMFs: Natco, Aurobindo, Cadila HC, Biocon, Intas, Alembic, Glenmark, Emcure, Shilpa Medi. MSN, Unichem, Honour Lab, megafine, Optimus, Raks, Formosa, Pharmazell, Olon, Tianjin Weijie
Para-IVs	Alembic, Alvogen, Apotex, Aurobindo, Teva, Biocon, Breckenridge, Hetero, Mylan, Amneal, Emcure, Par Pharma, Accord (Intas), MSN Labs, Watson, Zydus Cadila, Glenmark, Torrent
Launch	Generic launch : Mar-2023
Settlement	In 2017, Sanofi reached settlement with all 20 generic Aubagio® ANDA first filers granting each a royalty-free license to enter the United States market on March 12, 2023.
DMFs	Total 19 DMFs: Natco, Aurobindo, Cadila HC, Biocon, Intas, Alembic, Glenmark, Emcure, Shilpa Medi. MSN, Unichem, Honour Lab, megafine, Optimus, Raks, Formosa, Pharmazell, Olon, Tianjin Weijie
Generic companies involved in patent litigations:	Accord HC, Intas, Alembic, Alvogen, Amneal, Apotex, Aurobindo, Biocon, Breckenridge, Cadila HC, Emcure, Heritage, Glenmark, Hetero, MSN, Mylan, Par (Endo), Teva, Torrent

Figure-90: Patent expiry in the US

Type of patent	US
Compound	Expired
Later filed patents	Coverage ranging through February 2034
Regulatory exclusivity	September 2017

Figure-91: Sanofi: Aubagio US Sales, USD mn. Sharp decline in CY23.

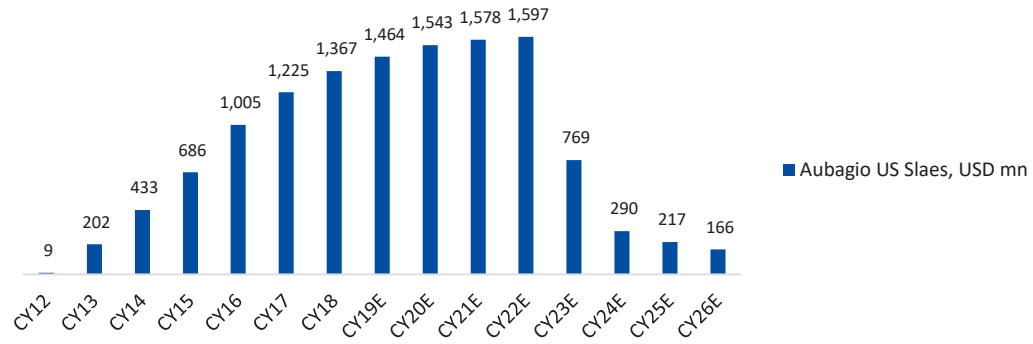


Figure-92: Teriflunomide DMFs

Submit Date	Holder (Teriflunomide)
1/29/2014	MSN Laboratories Private Ltd
3/16/2016	Alembic Pharmaceuticals Ltd
3/20/2015	Glenmark Pharmaceuticals Ltd
10/1/2015	Honour Lab Ltd
9/29/2015	Unichem Laboratories Ltd
9/29/2015	Megafine Pharma P Ltd
9/18/2015	Optimus Drugs Private Ltd
10/21/2015	Raks Pharma Pvt Ltd
12/30/2015	Formosa Laboratories Inc
3/10/2016	Pharmazell Gmbh
3/5/2016	Biocon Ltd
3/15/2016	Aurobindo Pharma Ltd
3/7/2016	Olon Spa
3/29/2016	Emcure Pharmaceuticals Ltd
4/1/2016	Cadila Healthcare Ltd
4/21/2016	Intas Pharmaceuticals Ltd
4/29/2016	Natco Pharma Ltd
11/10/2016	Tianjin Weijie Pharmaceutical Co Ltd
11/4/2017	Shilpa Medicare Ltd

Figure-93: Aubagio Patent Litigation

Date	ANDA Filer	Aubagio Patent no.
D. Del. Dec. 30, 2016	Torrent Pharma Inc.; Torrent Pharmaceuticals Ltd.	6,794,410; 9,186,346
D. Del. Dec. 30, 2016	Emcure Pharmaceuticals Ltd.; Heritage Pharma Labs Inc.; Heritage Pharmaceuticals Inc.	9,186,346
D. Del. Dec. 29, 2016	Glenmark Pharmaceuticals Inc., USA; Glenmark Pharmaceuticals Ltd.; Glenmark Pharmaceuticals SA	6,794,410; 9,186,346
D. Del. Dec. 28, 2016	Alembic Pharmaceuticals Ltd.; Alembic Global Holding SA; Alembic Ltd.; Alembic Pharmaceuticals, Inc.	6,794,410; 9,186,346
D. Del. Dec. 27, 2016	Apotex, Inc.; Apotex Corp.	6,794,410; 9,186,346
D. Del. Dec. 27, 2016	Accord Healthcare, Inc.; Accord Healthcare Ltd.; Intas Pharmaceuticals Ltd.	6,794,410; 9,186,346
D. Del. Dec. 22, 2016	Alvogen Pine Brook LLC	6,794,410; 9,186,346
D. Del. Dec. 22, 2016	Aurobindo Pharma USA, Inc.; Aurobindo Pharma Ltd.	6,794,410; 9,186,346
D. Del. Dec. 22, 2016	Watson Laboratories, Inc.; Teva Pharmaceuticals USA, Inc.	6,794,410; 9,186,346
D. Del. Jan. 25, 2017	Emcure Pharmaceuticals Ltd.; Heritage Pharma Labs Inc.; Heritage Pharmaceuticals Inc.	6,794,410
D. Del. Jan. 12, 2017	Par Formulations Private Ltd.; Par Pharmaceutical Cos., Inc.; Par Pharmaceutical, Inc.	6,794,410; 8,802,735; 9,186,346
D. Del. Jan. 12, 2017	Amneal Pharmaceuticals Co. India Private Ltd.; Amneal Pharmaceuticals LLC	6,794,410; 8,802,735; 9,186,346
N.D. W.Va. Jan. 12, 2017	Mylan Pharmaceuticals Inc.; Mylan Inc.	6,794,410; 8,802,735; 9,186,346
D. Del. Jan. 11, 2017	Zydus Pharmaceuticals (USA) Inc.; Cadila Healthcare Ltd.	8,802,735; 9,186,346
D. Del. Jan. 11, 2017	Hetero USA Inc.; Hetero Labs Ltd.	6,794,410; 8,802,735; 9,186,346
D. Del. Jan. 10, 2017	MSN Laboratories Private Ltd.; MSN Pharmaceuticals Inc.	6,794,410; 8,802,735; 9,186,346
D. Del. Jan. 10, 2017	Mylan Pharmaceuticals Inc.; Mylan Inc.	6,794,410; 8,802,735; 9,186,346
D. Del. Jan. 5, 2017	Breckenridge Pharmaceutical, Inc.	6,794,410; 8,802,735; 9,186,346
D. Del. Jan. 5, 2017	Teva Pharmaceutical Industries Ltd.; Teva Pharmaceuticals USA, Inc.	6,794,410
D. Del. Jan. 3, 2017	IMPAX Laboratories, Inc.	6,794,410; 9,186,346
D. Del. Jan. 3, 2017	Biocon Ltd.	6,794,410; 9,186,346

Sovaldi
sofosbuvir

Sovaldi is no more a meaningful opportunity. Multiple reasons:

(a) Shift to newer therapies Sovaldi -> Harvoni, -> Epclusa, Also approval of Vosevi.

(b) Authorized Generic launch of Harvoni and Epclusa in Jan-2019

(c) For CY18, Sovaldi had insignificant sales in the US (not disclosed by Gilead, BB: USD 24 mn)

Figure-94: Sovaldi/Sofosbuvir Snapshot

Brand	Sovaldi
API	Sofosbuvir
Innovator/Marketer	Gilead Sciences
Indication	Hepatitis C
Dosage Form	Tablets
Strengths (innovator)	400mg
Initial Innovator Approval US	Dec-2013
Natco's Partner	---
Filing	In March 2018, Natco announced that they have filed an ANDA on Sovaldi which is a Para-IV FTF.
Settlement	Gilead reached an agreement with Teva (in 2018) and Natco (in 2019) to resolve the lawsuit, these agreements have been dismissed. The settlement agreements have been filed with the Federal Trade Commission and Department of Justice as required by law.
Patent Expiry in the US	2029
US Sales, CY18	For the US market, Gilead did not report sales for CY-2018 and CY-2017. Sales numbers should be weak/subdued. BB number is USD 24 mn for CY18.
Competitive landscape	Gilead also launched Authorised Generic versions of Harvoni and Epclusa in Jan-2019 through its entity Aseguea Therapeutics.
DMFs	DMFs: Total 10 DMFs. Teva, Mylan, Lupin, Laurus, Alembic, Beijing Huikang Boyuan Chemical, Topharman Shandong , Changzhou Pharma
Para-IVs	Natco, Teva
Generic companies involved in patent litigations:	Natco, Teva, INC Research (Syneos Health)

Figure-95: Hep-C Treatments by Gilead Sciences

		API/s				
Date	Brand	Sofosbuvir	Ledipasvir	Velpatasvir	Voxilaprevir	US Expiry
Dec-2013	Sovaldi	Yes	-	-	-	2029
Oct-2014	Harvoni	Yes	Yes	-	-	2030
June-2016	Epclusa	Yes	-	Yes	-	2032
July-2017	Vosevi	Yes	-	Yes	Yes	2034

Figure-96: Sofosbuvir DMFs

Submit Date	Holder / Sofosbuvir
12/24/2014	Beijing Huikang Boyuan Chemical Tech Co Ltd
8/31/2015	Topharman Shandong Co Ltd
9/1/2017	Mylan Laboratories Ltd
4/14/2017	Lupin Ltd
6/28/2017	Teva Pharmaceutical Industries Ltd
7/4/2017	Teva Pharmaceutical Industries Ltd
9/6/2017	Changzhou Pharmaceutical Factory
11/10/2017	Laurus Labs Ltd
9/30/2017	Alembic Pharmaceuticals Ltd
7/7/2019	Fuxin Long Rui Pharmaceutical Co Ltd

Figure-97: Sovaldi US Sales, Gilead

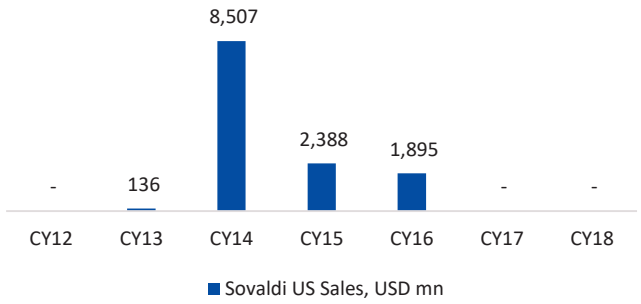


Figure-98: Hep-C Treatments from Gilead Sciences

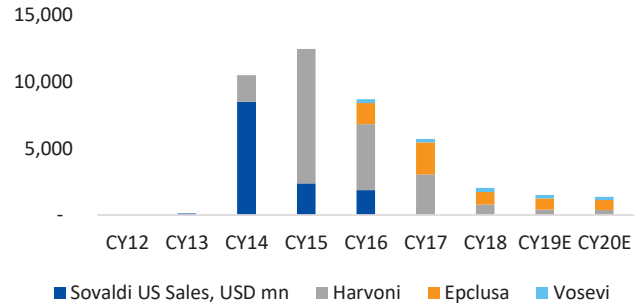


Figure-99: Hep-C Treatments from Gilead Sciences

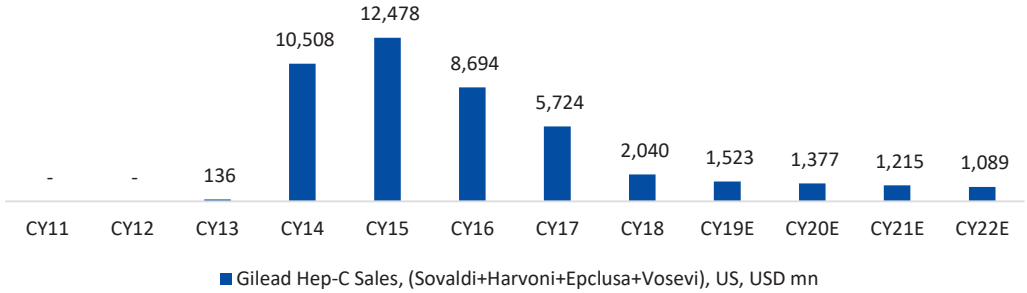


Figure-100: Gilead Sciences' Hep-C portfolio

Initial US Approval	Brand	APIs	US Expiry
Dec-2013	Sovaldi	Sofosbuvir	2029
Oct-2014	Harvoni	Sofosbuvir + Ledipasvir	2030
June-2016	Epclusa	Sofosbuvir + Velpatasvir	2032
July-2017	Vosevi	Sofosbuvir + Velpatasvir + Voxilaprevir	2034

Figure-101: DMFs for Gilead's Hep-C products

Brand	API-01	API-02	API-03	DMFs	DMF - players
Sovaldi	Sofosbuvir	-	-	Sofosbuvir: Total 10 DMFs	Sofosbuvir: Teva, Mylan, Lupin, Laurus, Alembic, Beijing Huikang Boyuan Chemical, Topharman Shandong , Changzhou Pharma
Harvoni	Sofosbuvir	Ledipasvir	-	Ledipasvir: Total 2 DMF	Ledipasvir: Mylan, Fuxin Long Rui
Epclusa	Sofosbuvir	Velpatasvir	-	Velpatasvir: -----No DMF	Velpatasvir: No DMF
Vosevi	Sofosbuvir	Velpatasvir	Voxilaprevir	Voxilaprevir: -----No DMF	Voxilaprevir: No DMF

Figure-102: Sovaldi Patent Litigation

Date	ANDA Filer	Sovaldi Patent no.
D. Del. Mar. 27, 2018	Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd.	7,429,572; 7,964,580; 8,334,270; 8,415,322; 8,580,765; 8,618,076; 8,629,263; 8,633,309; 8,642,756; 8,735,569; 8,889,159; 9,085,573; 9,206,217; 9,284,342; 9,340,568; 9,549,941; 9,637,512
D.N.J. Mar. 26, 2018	Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd.	7,429,572; 7,964,580; 8,334,270; 8,415,322; 8,580,765; 8,618,076; 8,629,263; 8,633,309; 8,642,756; 8,735,569; 8,889,159; 9,085,573; 9,206,217; 9,284,342; 9,340,568; 9,549,941; 9,637,512
D. Del. Mar. 16, 2018	Natco Pharma Ltd.; Natco Pharma Inc.; INC Research, LLC	7,429,572; 8,415,322; 8,618,076; 9,206,217; 9,284,342; 9,340,568
D.N.J. Mar. 14, 2018	Natco Pharma Ltd.; Natco Pharma Inc.; INC Research, LLC	7,429,572; 8,415,322; 8,618,076; 9,206,217; 9,284,342; 9,340,568

Zytiga
abiraterone acetate

Generics have started to enter from Nov-2018, several in market already. No more an opportunity.
In November 2018, the United States Court of Appeals for the Federal Circuit denied Janssen's request for an injunction pending appeal. As a result, several generic versions of Zytiga entered the market.

Figure-103: Zytiga / Abiraterone snapshot

Brand	Zytiga
API	Abiraterone
Innovator/Marketer	J&J
Indication	Oncology / prostate cancer
Dosage Form	Tablets
Strengths (innovator)	250mg, 500mg
Initial Innovator Approval US	Apr-2011
Natco's Partner	----
Filing	Para-IV
Settlement	No
Patent Expiry in the US	Already generic
US Sales, CY18	US Sales, 2018: USD 1.8 bn, CY19E: USD 680 mn, CY20E: USD 340 mn For H1CY19, sales down 57% YoY to USD 383 mn - impact of generic launches
Competitive landscape	Generics: Already launched: Teva, Mylan, Hikma, Apotex, Wockhardt, Amneal
DMFs	Total 24 DMFs Teva, Sun Pharma, Cipla, Dr Reddys, Hetero, MSN, Optimus, Raks, Optimus Drugs, Chongqing Pharma, Hubei Biocause Heilen, Tianjin Weijie Pharma, Qilu Antibiotics Linyi Pharma, Alp Pharm Beijing, Sterling Spa, Olon Spa, Chemwerth Inc, Sterling Chemical Malta, Zach System Sa,Industriale Chimica Srl, Scinopharm Taiwan, Aurisco Pharma, Iceutica Inc
Para-IVs	Actavis, Amneal, Apotex, Dr Reddy's, Hikma, Mylan, Par Pharma, Sun Pharma, Teva, Citron Pharma, Westward Pharma, Amerigen Pharma, Glenmark, Wockhardt, MSN Labs, Qilu Pharma
Generic companies involved in patent litigations:	Mylan, Teva, Amneal, Apotex, Dr Reddy's, Sun Pharma, West-Ward Pharmaceutical Corp. (Hikma), Wockhardt, Amerigen, Glenmark, MSN, Qila

Figure-104: J&J Zytiga US Sales, USD mn, major decline in CY19 due to generics entry

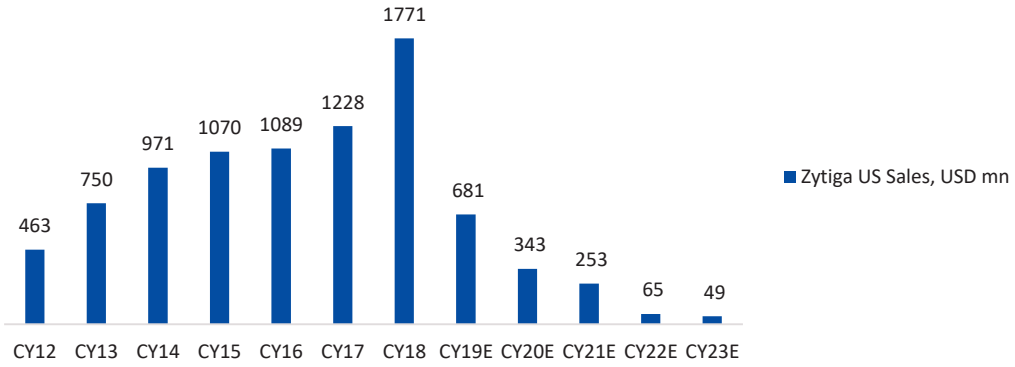


Figure-105: Abiraterone DMFs

Submit	Holder (Abiraterone)
11/28/2012	Sterling Spa
12/24/2012	Chongqing Pharmaceutical Research Institute Co Ltd
7/30/2014	Chemwerth Inc
8/1/2013	Olon Spa
12/24/2013	Msn Laboratories Private Ltd
12/24/2013	Hubei Biocause Heilen Pharmaceutical Co Ltd
2/12/2014	Sterling Chemical Malta Ltd
3/27/2014	Dr Reddys Laboratories Ltd
6/24/2014	Alp Pharm Beijing Co Ltd
6/13/2014	Hetero Labs Ltd
7/7/2014	Zach System Sa
10/8/2014	Industriale Chimica Srl
10/30/2014	Teva Pharmaceutical Industries Ltd
10/30/2014	Optimus Drugs Private Ltd
11/5/2014	Optimus Drugs Private Ltd
12/23/2014	Raks Pharma Pvt Ltd
2/11/2015	Sun Pharmaceutical Industries Ltd
3/31/2015	Cipla Ltd
6/1/2016	Scinopharm Taiwan Ltd
3/3/2017	Aurisco Pharmaceutical Co Ltd
4/25/2017	Iceutica Inc
4/12/2017	Tianjin Weijie Pharmaceutical Co Ltd
2/24/2018	Qilu Antibiotics Linyi Pharmaceutical Co Ltd
3/26/2018	MSN Laboratories Private Ltd

Figure-106: Zytiga Patent Litigation

Date	ANDA Filer	Zytiga Patent no.
D.N.J. July 31, 2015	Actavis Laboratories FL Inc.; Actavis Pharma Inc.; Actavis Inc.; Amneal Pharmaceuticals LLC; Amneal Pharmaceuticals of New York LLC; Apotex Corp.; Apotex Inc.; Citron Pharma LLC; Dr. Reddy's Laboratories Inc.; Dr. Reddy's Laboratories Ltd.; Mylan Pharmaceuticals Inc.; Mylan Inc.; Par Pharmaceutical Inc.; Par Pharmaceutical Cos.; Sun Pharmaceutical Industries Ltd.; Sun Pharmaceuticals Industries Inc.; Teva Pharmaceuticals USA Inc.; Teva Pharmaceutical Industries Ltd.; West-Ward Pharmaceutical Corp.; Arab Pharmaceutical Manufacturing Co.; Hikma Pharmaceuticals PLC; Hikma Pharmaceuticals LLC; Wockhardt Bio AG; Wockhardt USA LLC; Wockhardt Ltd.	5,604,213; 8,822,438
N.D. W. Va. Aug. 4, 2015	Mylan Pharmaceuticals Inc.; Mylan Inc.	8,822,438
D. Del. Aug. 3, 2015	Amneal Pharmaceuticals LLC; Amneal Pharmaceuticals of New York LLC; Par Pharmaceutical Inc.; Par Pharmaceutical Companies Inc.	8,822,438
D.N.J. May 2, 2016	Amerigen Pharmaceuticals Ltd.; Amerigen Pharmaceuticals, Inc.	U.S. Patent No.8,822,438
D.N.J. Jun. 24, 2016	Glenmark Pharmaceuticals Inc., USA; Glenmark Pharmaceuticals Ltd.; Glenmark Pharmaceuticals SA	8,822,438
D.N.J. Aug. 25, 2017	Teva Pharmaceuticals USA, Inc.; Teva Pharmaceuticals Industries, Ltd.	8,822,438
D.N.J. Feb. 20, 2018	MSN Pharmaceuticals Inc.; MSN Laboratories Private Ltd.	8,822,438
D.N.J. Nov. 28, 2018	Qilu Pharmaceutical Co., Ltd.; Qilu Pharma, Inc.	8,822,438

Tarceva
erlotinib

No longer an opportunity. Mylan and Teva have already launched generic version in May-2019.
For H1CY19, US sales for Tarceva down ~50% primarily due to generic launches. Teva and Mylan had settled in Mar-2011 and in July-2013 respectively. In May-2019, Teva which had a Para-IV on Tarceva launched the generic version. Mylan also launched generic version around the same time.

Figure-107: Tarceva / Erlotinib snapshot

Brand	Tarceva
API	Erlotinib
Innovator/Marketer	OSI Pharmaceuticals (now Astellas) + Pfizer, Roche
Oncology / Cancer	Oncology / Cancer
Dosage form	Tablets
Strengths (innovator)	25mg,100mg,150 mg
Initial Innovator Approval	Nov-2004
Natco's Partner	Breckenridge Pharma
Filing	Para-IV
Settlement	Settled with Teva and Mylan; Not with Natco
Natco's generic launch	No clarity
Patent Expiry in the US	----------
Settlement timelines	No settlement with Natco/Breckenridge Pharma Teva and Mylan had settled in Mar-2011 and in July-2013 respectively
US Sales, CY18	US market size 2018 USD 238 mn, sales down YoY due to competitive pressures. For H1CY19, US sales for Tarceva down ~50%, competitive pressures + generic launches by Teva, Mylan (May-2019)
Competitive landscape	Teva, Mylan already in market.
DMFs	Total DMFs: 21. Teva, Apotex, Natco, Hetero, MSN, Shilpa, Reliance Life, Sun Pharma, Cipla, Intas, Alembic, MSN Labs, Sichuan Xili Pharma, Asymchem, ++
Para-IVs	Mylan, Teva, Roxane, Sun Pharma, Hetero, Intas (Accord), Natco (Breckenridge), Apotex, Shilpa Medicare, Zydus Cadila
Generic companies involved in patent litigations	Natco, Breckenridge, Teva, Mylan, Roxane (Hikma), Apotex, Sun Pharma, Hetero, Shilpa Medi

Figure-108: Tarceva US Sales, monthly, BB (indicative, USD mn)

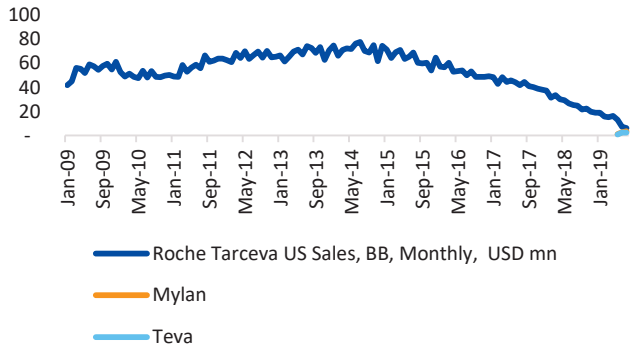


Figure-109: Tarceva – generic launches (monthly indicative sales, USD mn)

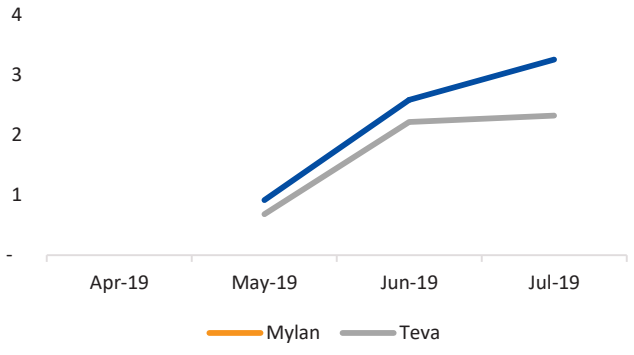


Figure-110: Roche - Tarceva US Sales, USD mn

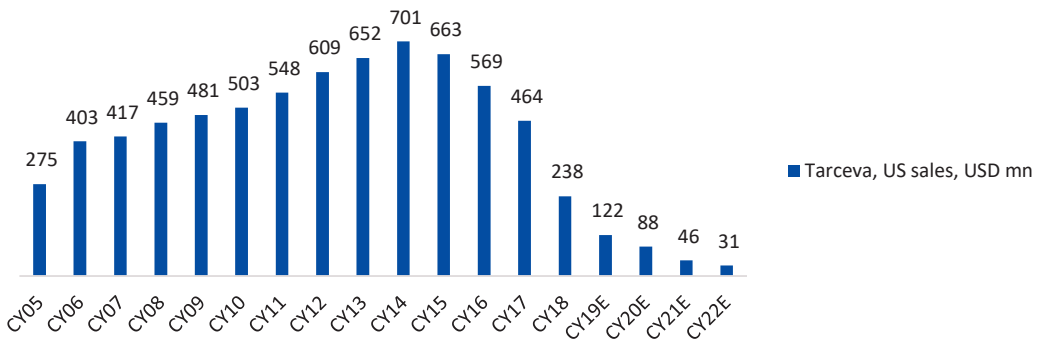


Figure-111: Erlotinib DMFs

Submit Date	Holder / Erlotinib
7/11/2008	Natco Pharma Ltd
7/27/2009	Tai Heng Industry Co Ltd
10/16/2009	Teva Pharmaceutical Industries Ltd
11/30/2009	Zhejiang Jiuzhou Pharmaceutical Co Ltd
12/28/2010	Mylan Laboratories Ltd
2/25/2011	Mylan Laboratories Ltd
8/6/2011	Cadila Healthcare Ltd Zyfine
10/2/2011	Cadila Healthcare Ltd
5/16/2012	Reliance Life Sciences Pvt Ltd
6/4/2012	Hetero Labs Ltd
9/12/2012	Sichuan Xieli Pharmaceutical Co Ltd
1/22/2013	Apotex Pharmachem Inc
5/31/2013	Msn Laboratories Private Ltd
1/5/2015	Asymchem Life Science Tianjin Co Ltd
4/13/2015	Shilpa Medicare Ltd
6/30/2015	Esteve Huayi Pharmaceutical Co Ltd
5/28/2015	Hikma Pharmaceuticals Plc
9/1/2015	Cipla Ltd
9/21/2015	Qilu Antibiotics Linyi Pharmaceutical Co Ltd
9/16/2015	Cambrex Charles City Inc
3/30/2016	Alembic Pharmaceuticals Ltd
8/29/2016	Intas Pharmaceuticals Ltd
12/15/2016	Sun Pharmaceutical Industries Ltd
12/18/2017	Fis Fabbrica Italiana Sintetici Spa
12/30/2017	Msn Laboratories Private Ltd
9/29/2018	Acebright India Pharma Private Ltd

Figure-112: Tarceva Patent Litigation

Date	ANDA Filer	Patent no.
D. Del. Mar. 19, 2009	Teva Pharmaceuticals USA, Inc.	5,747,498; 6,900,221;7,087,613
D. Del. Mar. 19, 2009	Mylan Pharmaceuticals, Inc.	5,747,498; 6,900,221;7,087,613
D. N.J. Apr. 20, 2012	Roxane Laboratories, Inc.	RE41,065; 6,900,221; 7,087,613
D. Del. Apr. 13, 2012	Roxane Laboratories, Inc.	RE41,065; 6,900,221; 7,087,613
D. Del. May 23, 2012	Roxanne Laboratories, Inc.	RE41,065; 6,900,221; 7,087,613
D. Del. Dec. 7, 2012	Roxane Laboratories Inc.	RE41,065; 6,900,221; 7,087,613
D. Del. Sept. 2, 2015	Apotex Inc.; Apotex Corp.	6,900,221
D. Del. Nov. 17, 2015	Breckenridge Pharmaceutical Inc.; Natco Pharma Ltd.	RE41,065; 6,900,221
D. Del. Jun. 1, 2017	Sun Pharmaceuticals Industries Inc.; Sun Pharmaceuticals Industries Ltd.	6,900,221
D. Del. Jun. 1, 2017	Hetero USA Inc.; Hetero Labs Ltd.; Hetero Labs Ltd. Univ-V	6,900,221
D. Del. Jul. 25, 2018	Shilpa Medicare Ltd.	6,900,221
D. Del. Apr. 25, 2019)	Zydus Pharmaceuticals (USA) Inc.	U.S. Patent No. 6,900,221

Tykerb
lapatinib

No clarity on the legal status despite it being an 8+ years old filing. Earlier in Mar-2015, Tykerb was expected to be a 'limited competition' opportunity.

It's an old filing (June 2011). There is no update from innovators or generic players, or other resources (BB Law, media), etc. Market size less than USD 100 mn.

Figure-113: Tykerb / Lapatinib snapshot

Brand	Tykerb
API	Lapatinib
Innovator/Marketer	Novartis / (earlier wth GSK)
Indication	Oncology / Breast cancer
Dosage Form	Tablets
Strengths (innovator)	250 mg
Initial Innovator Approval	Mar-2007
Natco's Partner	Lupin
Filing	Para-IV/FTF, disclosed in 2011
Settlement	No
Patent Expiry in the US	----
US Sales, CY18	CY18 US Sales not disclosed by Novartis (since the drug is not in Top-20 in the US). BB CY18 Sales: USD 86 mn. CY18 company level sales is likely to be close to BB recorded sales - less than USD 100 mn Natco FY16 AR: US Sales last 12 months USD 73 mn.
Competitive landscape	na
DMFs	Total 6 DMFs: Hetero, Formosa Labs, Delmar Chemicals, Cambrex Charles City, Alp Pharm Beijing, Scinopharm Taiwan
Generic companies involved in patent litigations:	Natco No litigation related disclosures on BB Law. No litigation related update from Novartis, GSK in their SEC filings.

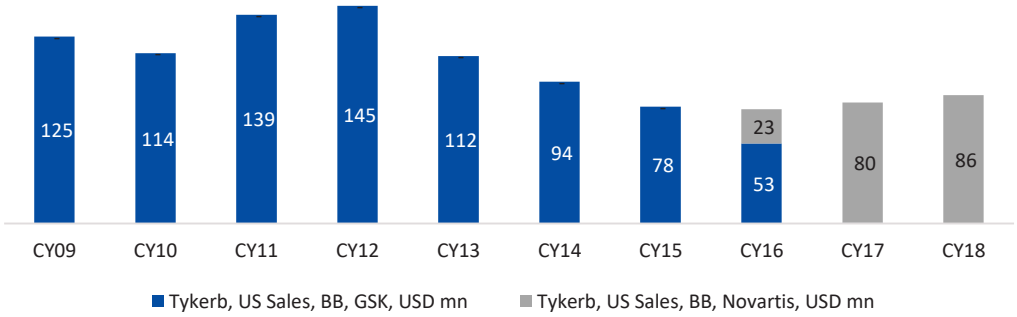
Figure-114: Lapatinib DMFs

Submit Date	Holder (Lapatinib)
3/18/2011	Formosa Laboratories Inc
9/20/2012	Sichuan Xieli Pharmaceutical Co Ltd
10/1/2013	Hetero Labs Ltd
9/10/2015	Alp Pharm Beijing Co Ltd
9/15/2015	Cambrex Charles City Inc
12/4/2015	Scinopharm Taiwan Ltd
1/17/2018	Delmar Chemicals Inc

Figure-115: Patent expiries beginning Jan-2019

Date	Patent
08-Jan-19	Bicyclic heteroaromatic compounds as protein tyrosine kinase inhibitors
08-Jan-19	Bicyclic heteroaromatic compounds as protein tyrosine kinase inhibitors
29-Sep-20	Heterocyclic compounds
29-Sep-20	Heterocyclic compounds
19-Nov-21	Quinazoline ditosylate salt compounds
08-Jan-19	Bicyclic heteroaromatic compounds as protein tyrosine kinase inhibitors
18-Sep-29	Pharmaceutical composition
06-Dec-21	Exclusivity expiration dates

Figure-116: Tykerb US sales (indicative), BB



Imbruvica
Ibrutinib

Currently under litigation (tablet form). Limited attractiveness in case of success. Recent filing, not a near-term opportunity.

For other dosage forms (capsule), the innovator has entered into a settlement agreement with generic companies (Teva, Hetero, Shilpa). There is no settlement on the tablet form. Hence, for now, to that extent, the attractiveness of the tablet version is limited. Consensus numbers for US shows growth till CY24, thereafter a gradual decline indicating no expectation of generic launch. Natco's filing is of January 2019. In the best case scenario, a generic launch is likely expected only after a few years.

Figure-117: Imbruvica / Ibrutinib snapshot

Brand	Imbruvica
API	Ibrutinib
Innovator/Marketer	AbbVie (Pharmacyclics), J&J. In the US, Imbruvica is marketed by both AbbVie (Pharmacyclics) and J&J (Janssen)
Indication	Oncology / Cancer
Dosage Form	Tablets, Capsules
Strengths (innovator)	Tablets: 140, 280, 420, 560 mg Capsules: 70, 140 mg
Initial Innovator Approval	Nov-2013
Natco's Partner	Alvogen (involved in co-development as well)
Natco's Filing	Para-IV / FTF on Tablet dosage form. Filed in Jan-2019
Settlement	No settlement with Natco (Tablet dosage form). Settlement with a few generic companies - Teva, Hetero and Shilpa (for Capsule dosage form). Terms of the settlement are not disclosed. Some reports suggest settlement with Fresenius Kabi.
Natco/Alvogen's generic launch	Under litigation. No settlement. No visible launch date. Not likely in the next few years.
Patent Expiry in the US	-----
US Sales, CY18	USD 4 bn (AbbVie USD 2.9 bn + J&J USD 1.1bn) For CY2018, AbbVie's sales break-up: 83% Tablet, 17% Capsule
Competitive landscape	In case of Natco/Alvogen's launch, it is highly likely that Teva, Hetero and Shilpa would have already been there on the market with the Capsule version. Hence, in case of success, the attractiveness is limited.
Settlement timelines	J&J SEC Filing Q2CY2019: In February 2019, Pharmacyclics and JBI (Janssen Biotech Inc.) entered into settlement agreements with Teva and Hetero. In March 2019, Pharmacyclics and JBI entered into a settlement agreement with Shilpa.
Generic companies involved in patent litigation: Tablet and / Or Capsule:	Natco, Alvogen, Teva, Cadila HC, Sandoz, Tek, Cipla, Shilpa Medicare, Sun Pharma, Fresenius Kabi, Hetero
DMFs	Total 15 DMFs: Teva, Natco, Sun Pharma, Dr Reddy's, Alembic, Hetero, Shilpa Medi, MSN, Fresenius Kabi, Perrigo API, Wisdom Pharma, Esteve Huayi, Scinopharm Taiwan

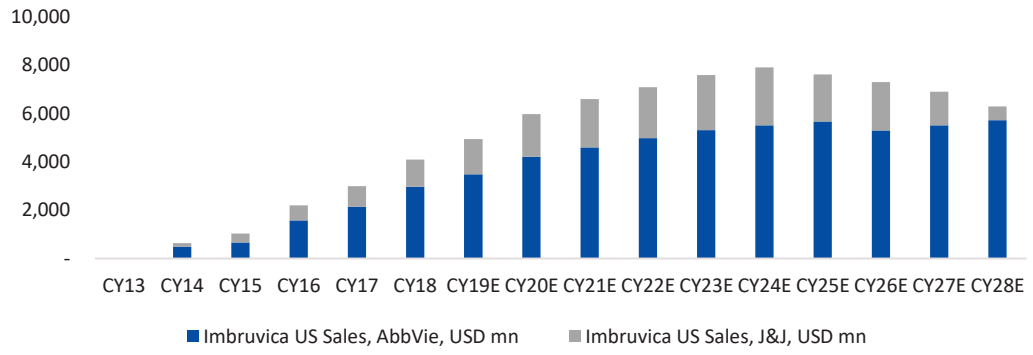
Figure-118: Ibrutinib DMFs

Submit Date	Holder (Ibrutinib)
5/31/2016	MSN Laboratories Private Ltd
8/16/2016	Perrigo Api Ltd
7/31/2016	MSN Laboratories Private Ltd
12/23/2016	Scinopharm Taiwan Ltd
5/12/2017	Fresenius Kabi Oncology Ltd
9/8/2017	Sun Pharmaceutical Industries Ltd
6/8/2017	Teva Pharmaceutical Industries Ltd
5/5/2017	Esteve Huayi Pharmaceutical Co Ltd
8/1/2017	Hetero Labs Ltd
7/3/2017	Cipla Ltd
6/23/2017	Dr Reddys Laboratories Ltd
7/20/2017	Wisdom Pharmaceutical Co Ltd
10/4/2017	Shilpa Medicare Ltd
7/2/2018	Alembic Pharmaceuticals Ltd
8/17/2018	Natco Pharma Ltd
12/1/2018	MSN Laboratories Ltd

Figure-119: Imbruvica Patent Litigatiion

Date	ANDA Filer	Imbruvica Patent no.
D. Del. Feb. 16, 2018	Zydus Worldwide DMCC; Cadila Healthcare Ltd.; Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd.; Sandoz Inc.; Lek Pharmaceuticals d.d.	7,514,444; 8,008,309; 8,476,284; 8,497,277; 8,697 ,711; 8,735,403; 8,754,090; 8,754,091; 8,952,015; 8,957,079; 8,999,999; 9,125,889; 9,181,257; 9,296 ,753; 9,713,617; 9,725,455; 9,795,604; 9,801,881; 9,801,883; 9,814,721
D. Del. Feb. 12, 2018	Cipla Ltd.; Cipla USA Inc.	8,754,090; 9,125,889; 9,296,753; 9,540,382; 9,713 ,617; 9,725,455
D. Del. Feb. 9, 2018	Shilpa Medicare Ltd.; Sun Pharma Global FZE; Sun Pharmaceutical Industries Ltd.	8,999,999; 9,296,753; 9,725,455; 9,801,881; 9,801 ,883
D. Del. Feb. 1, 2018	Fresenius Kabi USA, LLC; Fresenius Kabi USA, Inc.; Fresenius Kabi Oncology Ltd.	7,514,444; 8,008,309; 8,476,284; 8,497,277; 8,697 ,711; 8,735,403; 8,754,090; 8,754,091; 8,952,015; 8,957,079; 9,181,257; 9,296,753; 9,540,382; 9,713 ,617; 9,725,455
D. Del. Oct. 5, 2018	Sun Pharma Global FZE; Sun Pharmaceutical Industries Ltd.	10,004,746
D. Del. Nov. 12, 2018	Hetero USA Inc.; Hetero Labs Ltd.; Hetero Labs Ltd. Unit-V	8,754,090; 9,296,753; 9,540,382; 9,713,617; 9,725 ,455
D. Del. Mar. 1, 2019	Alvogen Pine Brook LLC; Natco Pharma Ltd.	7,514,444; 8,008,309; 8,476,284; 8,497,277; 8,697 ,711; 8,735,403; 8,754,090; 8,754,091; 8,952,015; 8,957,079; 9,181,257; 9,296,753; 9,655,857; 9,725 ,455; 10,010,507; 10,106,548; 10,125,140
D. Del. Jan. 28, 2019	Zydus Worldwide DMCC; Cadila Healthcare Ltd.	7,514,444; 8,008,309; 8,476,284; 8,497,277; 8,697 ,711; 8,735,403; 8,754,090; 8,754,091; 8,952,015; 8,957,079; 9,181,257; 9,296,753; 9,725,455; 10,10 6,548; 10,125,140
D. Del. Jan. 4, 2019	Hetero USA Inc.; Hetero Labs Ltd.; Hetero Labs Ltd. Unit-V; Hetero Labs Ltd. Unit-I	10,106,548

Figure-120: Imbruvica / Ibrutinib US Sales for innovators (AbbVIe and J&J)



Tracleer
bosantan

Subject to litigation outcome/settlement. Tracleer, if successful could be a small opportunity. Generic versions launched for two strengths. Natco is looking for a lower strength pediatric version. Total market size (all strengths) is less than USD 100 mn. Pediatric strength could be USD 20-30 mn.

In June 2019, Hikma, Teva launched the generic version of regular strengths 62.5mg and 125mg. BB Shows Amneal and Cadila HC as well. Multiple ANDA approvals.
Natco's Para-IV/FTF filing is on 32mg version which is a pediatric one (tablet for suspension). No generic launch for 32mg version.

US Sales of USD 268 mn in 2018, a declining trend.

Sales under pressure due to shift to Opsumit (macitentan) and also other, non-bosentan generics for the same indication. Additionally, there is now a bosentan generic available for 62.5mg/125mg.

Sales of 32mg - small part in the overall pie (BB - 5% of CY18 numbers).

In May 2019, the innovator (J&J) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Natco Pharma and Syneos Health LLC (collectively, Natco), who filed an ANDA seeking approval to market a generic version of Tracleer 32 mg, before the expiration of U.S. Patent No. 8,309,126 (the '126 patent). In the lawsuit, Actelion (J&J) is seeking an order enjoining Natco from marketing its generic version of Tracleer before the expiration of the '126 patent.

For Q3CY2019, Tracleer sales (all strengths) in the US was at USD 19 mn (down 70%) impacted by generics and cannibalization from Opsumit (macitentan). Both Tracleer and Opsumit are endothelin receptor antagonists used in the treatment of pulmonary artery hypertension.

Based on Q3CY19 numbers, annualised size of Tracleer (all strengths) in the US is at USD 80 mn now (Vs 270mn in CY2018). Street expectations are at USD 125 mn for CY20.

Figure-121: Tracleer / Bosentan snapshot

Brand	Tracleer
API	Bosentan
Innovator/Marketer	Actelion Pharmaceuticals US, Inc. (acquired by Johnson & Johnson),
Indication	Pulmonary Arterial Hypertension (PAH)
Dosage Form	Tablets
Strengths (innovator)	62.5mg, 125 mg // 32 mg - paediatric
	62.5mg, 125 mg: Nov-2001
Initial Innovator Approval US	125 mg: Nov-2001, 32 mg - paediatric: Sept-2017
Natco's Partner	---
Natco's Para-IV filing strength	32 mg (paediatric)
Settlement	----
Natco generic launch	---
Patent Expiry in the US	----
US Sales, CY18	For CY18, Tracleer had registered sales of ~ USD 268mn in the US market (all three strengths)
	Q2CY2019: sales of Tracleer (bosentan) were negatively impacted by increased use of Opsumit and generics.
Competitive landscape / 32 mg	No generic yet
Competitive landscape / 62.5mg, 125mg	62.5mg, 125mg ANDA Approvals Alvogen, Amneal, Natco, Par Pharma (Endo), Sun Pharma, Watson Labs, West-Ward Pharms, Zydus/Cadila HC
DMFs	Total 18 DMFs Mylan, Zach System Spa, Alembic, Aminoc Chem, Aurobindo, Cadila HC, Cipla, Glenmark, Jubilant, Megafine, MSN, Neuland, Parabbolic Drugs, Raks Pharma, Sun Pharma, Zhejiang Medicine
Para-IVs	Natco
DMFs	Total 18 DMFs Mylan, Zach System Spa, Alembic, Aminoc Chem, Aurobindo, Cadila HC, Cipla, Glenmark, Jubilant, Megafine, MSN, Neuland, Parabbolic Drugs, Raks Pharma, Sun Pharma, Zhejiang Medicine
Generic companies involved in patent litigations:	Natco, Syneos

Figure 122: Tracleer Actelion, J&J Sales, USD mn. All strengths. Q3CY19 annualised USD 80 mn)

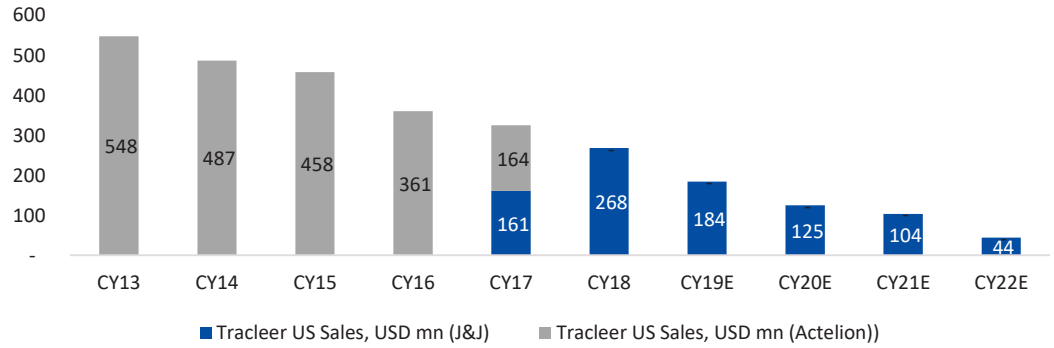


Figure-123: Tracleer Patent Litigation

Date	ANDA Filer	Bosentan Patent no.
D.N.J. May 28, 2019	Natco Pharma Ltd.; Syneos Health LLC	U.S. Patent No. 8,309,126

Figure-124: Bosentan DMFs

Submit Date	Holder /Bosentan
11/11/2009	Msn Laboratories Private Ltd
12/4/2009	Mylan Laboratories Ltd
1/14/2010	Amino Chemicals Ltd
12/23/2010	Sun Pharmaceutical Industries Ltd
9/9/2010	Glenmark Pharmaceuticals Ltd
5/9/2011	Zach System Spa
6/30/2011	Alembic Pharmaceuticals Ltd
7/15/2011	Tai Heng Industry Co Ltd
9/30/2011	Megafine Pharma P Ltd
4/2/2012	Cadila Healthcare Ltd
5/9/2012	Neuland Laboratories Ltd
5/28/2012	Parabolic Drugs Ltd
9/21/2012	Zhejiang Medicine Co Ltd Xinchang Pharmaceutical Factory
3/5/2013	Cadila Pharmaceuticals Ltd
2/14/2013	Aurobindo Pharma Ltd
9/9/2014	Jubilant Generics Ltd
3/3/2015	Chemwerth Inc
3/13/2015	Cipla Ltd
9/26/2019	Sun Pharmaceutical Industries Ltd
4/30/2018	Raks Pharma Pvt Ltd

Figure-125: Tracleer monthly sales, BB

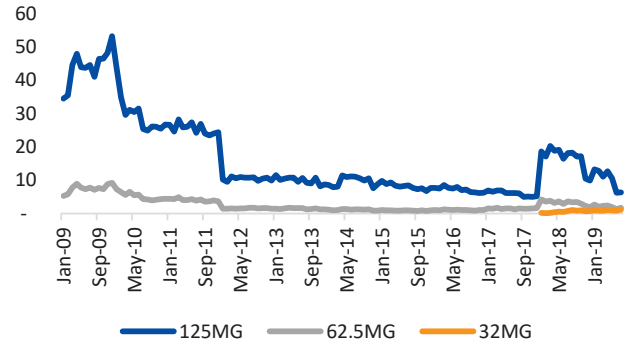


Figure-126: Tracleer monthly sales, BB

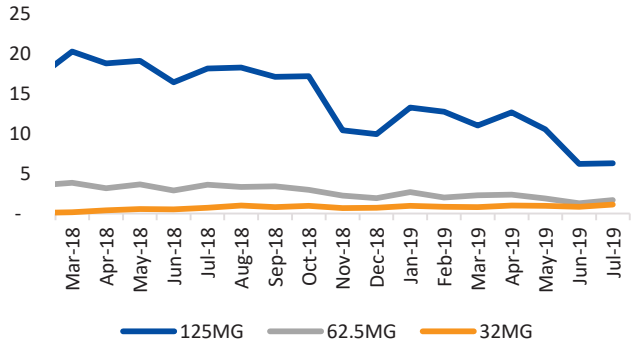


Figure-127: Tracleer 32mg, Monthly Sales, USD mn

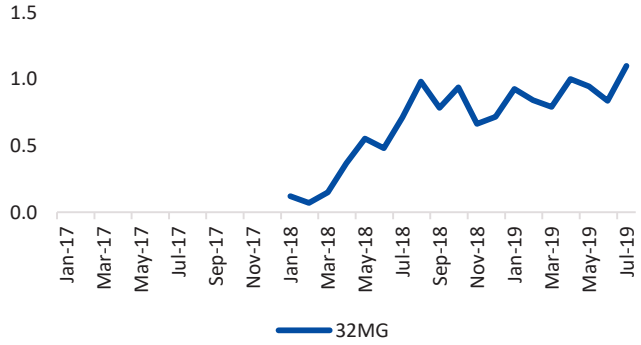
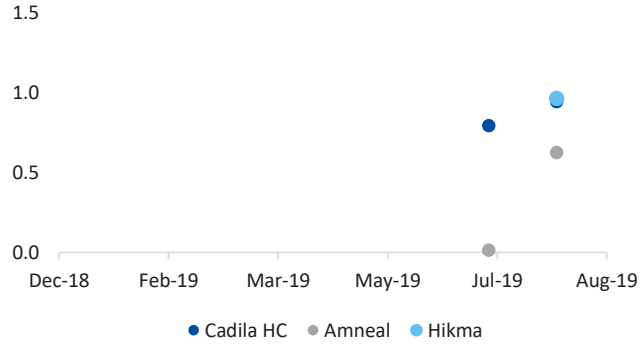


Figure 128: Tracleer generic 125mg and 62.5 mg strengths. Monthly Sales, USD mn. Cadila HC, Amneal, Hikma. Teva has also launched. USD mn. BB Monthly sales.



Pomalyst
pomalidomide

Under litigation.

The innovator has not settled with any generic company. 30-month stay ends on Aug.08, 2020. Multiple Para-IV filers. US Sales, 2018 USD 1.4 bn. U.S. drug substance/use patent expiry: 2025. Consensus estimates suggest generics launch in CY-2025, estimated sales declining from USD 2.7 in CY24E to USD 1.1 bn in CY25E.

As a result of the Celgene court filings, the FDA cannot grant final approval to the ANDs (P-IV, under litigation) until at least the earlier of (i) a final decision that each of the patents is invalid, unenforceable, and/or not infringed, and (ii) August 8, 2020 (30-month stay).
Para-IV filers: Teva, Apotex, Hetero, Aurobindo, Mylan, Breckenridge (Natco), Synthon, Dr Reddy's.

FTF: Not sure. Celgene notified Teva first followed by other generic companies. It's possible that Teva is the FTF.

Figure-129: Pomalyst / Pomalidomide snapshot

Brand	Pomalyst
API	pomalidomide
Innovator / Marketer	Celgene
Indication	Oncology / Cancer
Dosage form	Capsules
Strengths (innovator)	25mg,100mg,150 mg
Initial Innovator Approval	Feb-2013
Natco's partner	Breckenridge
Filing	Para-IV
Settlement	No settlement
Natco's generic launch	Under litigation
Patent expiry in the US-1	U.S. drug substance/use patent // 2025
Settlement timelines	na
US Sales, CY 2018, USD mn	USD 1.4 bn
Para-IVs	Hetero, Par Pharma, Teva, Apotex, Aurobindo, Mylan, Alvogen, Synthon Pharma, Breckenridge (Natco), Dr Reddy's
Generic companies involved in patent litigations:	Natco, Breckenridge, Teva, Mylan, Synthon, Apotex, Par (Endo), Aurobindo, Hetero, Dr Reddys,
DMFs	Total DMFs: 11 Mylan, Natco, Dr Reddys, Hetero, MSN, Shilpa, Cipla, Olon Spa, Synthon BV, Apicore, Tianjin Weijie

Figure-130: Celgene Pomalyst US Sales, USD mn. Generic launch is expected in CY25.

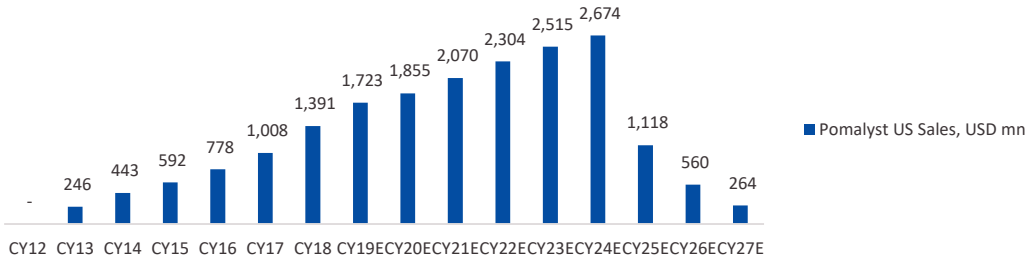


Figure-131: Pomalidomide DMFs

Submit Date	Holder
6/30/2015	Mylan Laboratories Ltd
3/30/2016	MSN Laboratories Private Ltd
5/10/2016	Olon Spa
7/14/2016	Hetero Labs Ltd
8/2/2016	Synthon Bv
10/18/2016	Apicore Us Llc
11/10/2016	Natco Pharma Ltd
4/28/2017	Dr Reddys Laboratories Ltd
4/11/2017	Tianjin Weijie Pharmaceutical Co Ltd
12/9/2017	Shilpa Medicare Ltd
10/1/2018	Cipla Ltd

Figure-132: Pomalyst Patent Litigation

Date	ANDA Filer	Pomalyst Patent no.
D.N.J. May 11, 2017	Hetero Labs Ltd.; Hetero Labs Ltd. Unit-V; Hetero Drugs Ltd.; Hetero USA, Inc.; Aurobindo Pharma Ltd.; Aurobindo Pharma USA, Inc.; Aurolife Pharma LLC; Eugia Pharma Specialities Ltd.; Apotex Inc.; Apotex Corp.; Mylan Pharmaceuticals, Inc.; Mylan Inc.; Mylan, N.V.; Breckenridge Pharmaceutical, Inc.	8,198,262; 8,673,939; 8,735,428; 8,828,427
D.N.J. May 4, 2017	Par Pharmaceutical, Inc.; Par Pharmaceutical Cos., Inc.; Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd.	8,198,262; 8,673,939; 8,735,428; 8,828,427
M.D.N.C. Jun. 21, 2018	Synthon Pharmaceuticals, Inc.; Synthon B.V.; Synthon s.r.o.; Alvogen Pine Brook, LLC	8,198,262; 8,673,939; 8,735,428; 8,828,427
D.N.J. Jun. 19, 2018	Synthon Pharmaceuticals, Inc.; Synthon B.V.; Synthon s.r.o.; Alvogen Pine Brook, LLC	8,198,262; 8,673,939; 8,735,428; 8,828,427
D.N.J. Sept. 27, 2018	Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd.	9,993,467
D.N.J. Sept. 20, 2018	Hetero Labs Ltd.; Hetero Labs Ltd. Unit-V; Hetero Drugs Ltd.; Hetero USA, Inc.	9,993,467
D.N.J. Oct. 5, 2018	Breckenridge Pharmaceutical, Inc.; Natco Pharma Ltd.	9,993,467
D.N.J. Nov. 21, 2018	Apotex Inc.	9,993,467
D.N.J. Nov. 9, 2018	Mylan Pharmaceuticals Inc.; Mylan Inc.; Mylan N.V.	9,993,467
D.N.J. Mar. 19, 2019	Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd.	10,093,647; 10,093,648; 10,093,649
D. Del. Feb. 14, 2019	Apotex Inc.	10,093,647; 10,093,648; 10,093,649
D. Del. Feb. 14, 2019	Breckenridge Pharmaceutical, Inc.; Natco Pharma Ltd.	10,093,647; 10,093,648; 10,093,649
D.N.J. Feb. 14, 2019	Mylan Pharmaceuticals Inc.; Mylan Inc.; Mylan N.V.	10,093,647; 10,093,648; 10,093,649
D.N.J. Feb. 14, 2019	Aurobindo Pharma Ltd.; Aurobindo Pharma USA, Inc.; Aurolife Pharma LLC; Eugia Pharma Specialities Ltd.	10,093,647; 10,093,648; 10,093,649
D.N.J. Feb. 14, 2019	Hetero Labs Ltd.; Hetero Labs Limited Unit-V; Hetero Drugs Ltd.; Hetero USA, Inc.	10,093,647; 10,093,648; 10,093,649
D.N.J. Jan. 4, 2019	Aurobindo Pharma Ltd.; Aurobindo Pharma USA, Inc.; Aurolife Pharma LLC; Eugia Pharma Specialities Ltd.	9,993,467
D.N.J. July 12, 2019	Dr. Reddy's Laboratories, Ltd.; Dr. Reddy's Laboratories, Inc.	U.S. Patent Nos. 8,198,262; 8,673,939; 8,735,428; 8,828,427; 9,993,467
D.N.J. Apr. 12, 2019	Synthon Pharmaceuticals, Inc.; Synthon B.V.; Synthon s.r.o.; Alvogen Pine Brook, LLC	U.S. Patent Nos. 10,093,647; 10,093,648; 10,093,649

Gilenya
fingolimod

No specific update from the innovator/ generic companies. Subject to litigation/settlement, the launch could be in CY20/CY21.

US Sales of USD 1.7 bn for CY18. ~flat YoY. Some competitive pressure in CY19E. CY20E sales decline is expected to be at USD 200+ mn, Sharp contraction of USD 500mn+ in CY21E.
Novartis disclosures do not indicate generics in CY19. Consensus numbers suggest a likely generic launch in CY20/21.

Multiple Para-IV filers, many companies involved in litigation.

Figure-133: Gilenya / Fingolimod snapshot

Brand	Gilenya
API	fingolimod
Innovator/marketer	Novartis (licensed from Mitsubishi Tanabe)
Indication	Multiple Sclerosis
Dosage Form	Capsule
Strengths (innovator)	0.5 mg
Initial Innovator Approval US	Sept-2010
Natco's Partner	---
Natco's filing	Para-IV/FTF
Natco's filing disclosure (date/month)	Feb-2015
Settlement	No
Patent Expiry in the US	-----
US Sales, CY18	US Sales of USD 1.7 bn for CY18
DMFs	Total 21 SMFs: Teva, Mylan, Apotex Sun Pharma, Dr Reddys'c, Cadila HC, Glenmark, Biocon, Alembic, Intas, Emcure, Shilpa, MSN, Honour Lab, HEC Pharma Co, Maprimed Sa, Zhejiang Huahai Pharma, Tai Heng Industry Co, Novugen Pharma (Malaysia)
Para-IVs	Apotex, HEC Pharma, Mylan, Ezra ventures, Aurobindo, Actavis, Accord (Intas), Alkem, Biocon, Bion pharma, Breckenridge, Dr Reddy's, Emcure, Glenmark, Hetero, MSN Labs, Nostrum Laboratories, Par Pharma, Prinston Pharma, Strides, Sun Pharma, Torrent, Zydus Cadila
Generic companies involved in patent litigations:	Actavis (Teva), Accord, Intas, Alembic, Alkem, Apotex, S&B, Aurobindo, Biocon, Bionpharma, Breckenridge Pharmaceutical, Standard Chemical & Pharma, Dr. Reddy's, Emcure, Heritage, Ezra Ventures, First Time US Generics LLC; Glenmark, HEC Pharm Co., Hetero, Mylan, Nostrum, MSN, Prinston, Strides, Torrent, Cadila HC, Sun Pharma

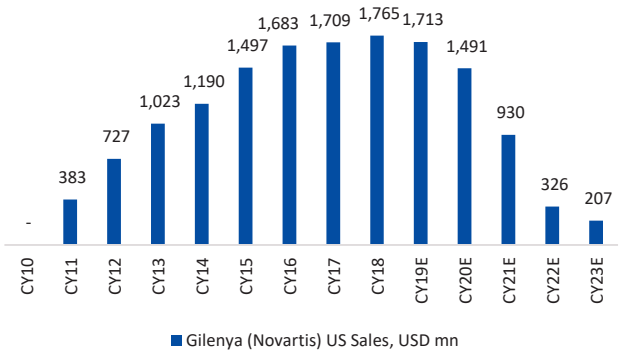
Figure-134: Gilenya Patent Litigation

Date	ANDA Filer	Gilenya Patent no.
D.N.J. Dec. 17, 2014	Actavis Inc.; Actavis Elizabeth LLC	5,604,229
D. Del. Dec. 16, 2014	Actavis Inc.; Actavis Elizabeth LLC	5,604,229
E.D. Ark. Feb. 13, 2015	Ezra Ventures LLC	5,604,229
D. Del. Feb 11, 2015	HEC Pharm Grp.; HEC Pharm Co.; HEC Pharm USA Inc.	5,604,229
D. Del. Feb 11, 2015	Ezra Ventures LLC	5,604,229
D.N.J. March 5, 2015	HEC Pharm Co.; HEC Pharm Grp.; HEC Pharm USA Inc.	5,604,229
S.D. Fla. Oct. 28, 2015	Apotex Inc.; Apotex Corp.	5,604,229
D. Del. Oct. 26, 2015	Apotex Inc.; Apotex Corp.	5,604,229
D. Del. Apr. 22, 2016	Mylan Pharmaceuticals Inc.; Mylan, Inc.	5,604,229
N.D. W.Va. May 18, 2016	Mylan Inc.; Mylan Pharmaceuticals, Inc.	5,604,229
D.N.J. Jan. 19, 2017	Aurobindo Pharma Ltd.; Aurobindo Pharma USA, Inc.	5,604,229
D. Del. Jan. 13, 2017	Aurobindo Pharma Ltd.; Aurobindo Pharma USA, Inc.	5,604,229
E.D. Va. Mar. 13, 2017	Alembic Pharms. Ltd	8,324,283
D. Del. Jul. 16, 2018	Accord Healthcare Inc.; Intas Pharmaceuticals Ltd.; Alkem Laboratories Ltd.; S&B Pharma, Inc.; Aurobindo Pharma Ltd.; Aurobindo Pharma USA, Inc.; Biocon Ltd.; Biocon Pharma, Inc.; Bionpharma Inc.; Breckenridge Pharmaceutical, Inc.; Standard Chemical & Pharmaceutical Co., Ltd.; Dr. Reddy's Laboratories, Inc.; Dr. Reddy's Laboratories, Ltd.; Emcure Pharmaceuticals; Heritage Pharmaceuticals Inc.; Ezra Ventures, LLC; First Time US Generics LLC; Glenmark Pharmaceuticals Inc., USA; Glenmark Pharmaceuticals Ltd.; HEC Pharm Co., Ltd.; HEC Pharm Group; HEC Pharm USA Inc.; Hetero USA Inc.; Hetero Labs Limited Unit-V; Hetero Labs Ltd.; Mylan Pharmaceuticals, Inc.; Nostrum Laboratories Inc.; Nostrum Pharmaceuticals, LLC; MSN Laboratories Private Ltd.; MSN Pharmaceuticals Inc.; Par Pharmaceutical Inc.; Prinston Pharmaceutical Inc.; Strides Global Pharma Private Ltd.; Strides Pharma, Inc.; Torrent Pharma Inc.; Torrent Pharmaceuticals Ltd.; Zydus Pharmaceuticals (USA) Inc.; Cadila Healthcare Ltd.	9,187,405
D. Del. Jul. 13, 2018	Sun Pharmaceutical Industries, Ltd.; Sun Pharmaceutical Industries, Inc.; Sun Pharma Global FZE	9,187,405
D. Del. Jul. 13, 2018	Teva Pharmaceuticals USA, Inc.; Actavis Elizabeth LLC	9,187,405
D. Del. Jul. 13, 2018	Apotex Inc.; Apotex Corp.	9,187,405

Figure-135: Fingolimod DMFs

Submit Date	Holder / Fingolimod
11/5/2012	Dr Reddys Laboratories Ltd
2/20/2013	Glenmark Pharmaceuticals Ltd
12/17/2013	Mylan Laboratories Ltd
12/30/2013	Msn Laboratories Private Ltd
3/28/2014	Apotex Pharmachem India Pvt Ltd
3/28/2014	Alembic Pharmaceuticals Ltd
4/23/2014	Tai Heng Industry Co Ltd
4/27/2014	Teva Pharmaceutical Ind. Ltd
5/30/2014	Shilpa Medicare Ltd
4/23/2014	Hec Pharm Co Ltd
4/22/2014	Honour Lab Ltd
6/19/2014	Emcure Pharmaceuticals Ltd
6/11/2014	Biocon Ltd
6/11/2014	Cadila Healthcare Ltd
7/10/2014	Sun Pharmaceutical Industries Ltd
7/8/2014	Maprimed Sa
6/19/2014	Zhejiang Huahai Pharmaceutical Co Ltd
6/24/2014	Intas Pharmaceuticals Ltd
12/30/2017	Msn Laboratories Private Ltd
3/1/2018	Msn Laboratories Private Ltd
12/24/2018	Novugen Pharma (Malaysia) Sdn Bhd

Figure-136: Novartis - Gilenya US Sales



Jevtana
cabazitaxel

Under litigation. Outcome dependent on the court's decision / settlement.

Innovator (Sanofi) or generic companies have not made any specific disclosures. If Natco/ Breckenridge wins the ongoing litigation or if there is any settlement, the launch timeline could be around Sept-2021.

Consensus US sales declining 40% YoY in CY21 and 37% YoY in CY22 to USD 140/90 mn. US compound patent 5847170 (the '170 patent) expiring in Sept-2021.

In Feb-2015, Breckenridge announced that it has filed an ANDA with a Para-IV certification for cabazitaxel solution; IV (infusion) in 60 mg/1.5 mL (40 mg/mL) strength. Breckenridge filed its Para-IV ANDA on the first-possible submission date and expects to be entitled to 180-day exclusivity. On January 14, 2015, Sanofi filed lawsuit against Breckenridge in the United States District Court for the District of New Jersey.

Sanofi has been in litigation with other generic players such as Actavis and Mylan as well. In Aug-2019, Sanofi won the appeal against the earlier court decision (which meant invalidating the '592 patent, which expires in 2031).

Figure-137: Jevtana/ Cabazitaxel snapshot

Brand	Jevtana
API	cabazitaxel
Innovator / Marketer	Oncology / Prostate Cancer
Indication	Sanofi
Dosage form	Injection
Strengths (innovator)	60 mg/1.5 mL (40 mg/mL)
Initial Innovator Approval	June-2010
Natco's partner	Breckenridge Pharma (disclosed by the partner)
Filing	Para-IV/FTF
Filing date/month	Jan-2015 (disclosed Feb-2015)
Settlement	No
Natco's generic launch	----
Settlement timelines	-----
US Sales, CY 2018, USD mn	CY18, US Sales of USD 211 mn
Competitive landscape	-----
DMFs	Total 12 DMFs Dr Reddys, Hetero, Intas, Laurus, MSN Labs, Polymed Therapeutics, Qilu Pharma, Sanofi Chimie, Teva, Tianjin Weijie Pharma
Para-IVs	Accord (Intas), Actavis, Apotex, Dr Reddy's, Fresenius Kabi, Glenmark, Sandoz, BPI Labs, Breckenridge (Natco), Mylan
Generic companies involved in patent litigations:	Accord Healthcare, Actavis (now, Teva), Apotex, Belcher Pharma, BPI Labs LLC; Breckenridge Pharma, Dr. Reddy's, Fresenius Kabi, Glenmark, Onco Therapies, Sandoz
TAs	Breckenridge : Tentative ANDA Approval: July-2019 Tentative approvals for multiple other companies: Apotex, BPI Labs, Mylan, Accord (Intas), Actavis (Teva), Sandoz

Figure-138: Jevtana/Cabazitaxel patent expiry

Patent	United States
Compound patent	September 2021 with PTE* and pediatric exclusivity
Later filed patents	coverage ranging through April 2031 with pediatric exclusivity

5,847,170 (the '170 patent): September 26, 2021
7,241,907 (the '907 patent): June 10, 2026
8,927,592 (the '592 patent): April 27, 2031
– PTE: Patent Term Extension. – SPC: Supplementary Protection Certificate. – PTA: Patent Term Adjustment.

Figure-139: Jevtana Patent Litigation

Date	ANDA Filer	Jevtana Patent no.
M.D. Fla. Dec. 30, 2014	BPI Labs LLC; Belcher Pharmaceuticals LLC	5,847,170
D. Del. Dec. 30, 2014	Fresenius Kabi USA LLC	5,847,170; 7,241,907
D.N.J. Dec. 29, 2014	Fresenius Kabi USA LLC	5,847,170; 7,241,907
D.N.J. Dec. 29, 2014	BPI Labs LLC; Belcher Pharmaceuticals LLC	5,847,170
D.N.J. Dec. 29, 2014	Accord Healthcare Inc.	5,847,170
D. Del. Dec. 18, 2014	Fresenius Kabi USA LLC	5,847,170; 7,241,907
D.N.J. Dec. 17, 2014	Fresenius Kabi USA LLC	5,847,170; 7,241,907
S.D. Fla. Jan. 15, 2015	Breckenridge Pharmaceutical Inc.	5,847,170; 7,241,907
D. Del. Jan. 15, 2015	Apotex Corp.; Apotex Inc.	5,847,170; 7,241,907
D.N.J. Jan. 14, 2015	Onco Therapies Ltd.	5,847,170; 7,241,907
D.N.J. Jan. 14, 2015	Breckenridge Pharmaceutical Inc.	5,847,170; 7,241,907
D.N.J. Jan. 14, 2015	Apotex Corp.; Apotex Inc.	5,847,170; 7,241,907
M.D.N.C. Jan. 7, 2015	Accord Healthcare Inc.	5,847,170
D.N.J. March 11, 2015	Breckenridge Pharmaceutical Inc.	8,927,592
D.N.J. March 11, 2015	Apotex Corp.; Apotex Inc.	8,927,592
D.N.J. April 13, 2015	Fresenius Kabi USA LLC	8,927,592
D.N.J. April 6, 2015	Glenmark Generics Inc.; Glenmark Pharmaceuticals Ltd.	8,927,592
D.N.J. April 6, 2015	Dr. Reddy's Laboratories Inc.; Dr. Reddy's Laboratories Ltd.	8,927,592
D.N.J. April 6, 2015	BPI Labs LLC; Belcher Pharmaceuticals LLC	8,927,592
D.N.J. April 6, 2015	Accord Healthcare Inc.	8,927,592
D.N.J. May 15, 2015	Onco Therapies Ltd.	8,927,592
D.N.J. May 1, 2015	Actavis LLC; Actavis Elizabeth LLC	8,927,592
D.N.J. Apr. 21, 2016	Dr. Reddy's Laboratories, Inc.; Dr. Reddy's Laboratories, Ltd.	5,847,170
D.N.J. Sep. 16, 2016	Sandoz Inc.	5,847,170; 8,927,592

Figure-140: Cabazitaxel DMFs

Submit Date	Holder
1/29/2010	Sanofi Chimie
2/7/2012	Polymed Therapeutics Inc
7/18/2013	Polymed Therapeutics Inc
9/26/2013	Qilu Pharmaceutical Co Ltd
3/3/2014	Msn Laboratories Private Ltd
2/18/2014	Dr Reddys Laboratories Ltd
2/20/2014	Intas Pharmaceuticals Ltd
4/1/2014	Teva Pharmaceutical Industries Ltd
4/21/2014	Hetero Labs Ltd
6/12/2014	Laurus Labs Ltd
5/26/2015	Msn Laboratories Private Ltd
12/5/2016	Tianjin Weijie Pharmaceutical Co Ltd

Figure-141: Jevtana US Sales, Sanofi

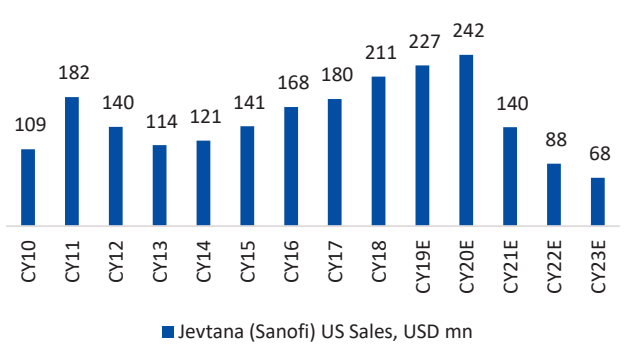
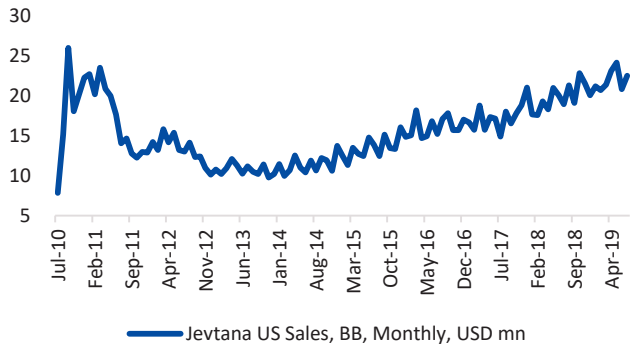


Figure-142: Jevtana US Sales, Monthly, BB



Lonsurf
trifluridine/tipiracil

Litigation just began. Subject to legal outcome, but not a near term opportunity. Recent filing (Nov-2019). Natco was sued in Jan-2020. Aurobindo in Dec-2019. Current street estimates for Lonsurf does not indicate generic launch till 2024.

Figure-143: Lonsurf / Trifluridine-Tipiracil snapshot

Brand	Lonsurf
API	trifluridine/tipiracil
Innovator/Marketer	Taiho Pharma (Otsuka)
Indication	Oncology
Dosage Form	Tablets
Strengths (innovator) : trifluridine/tipiracil	15mg /6.14mg, 20mg /8.19mg
Initial Innovator Approval	Sept-2015
Natco's partner	-----
Filing	Para-IV / FTF
Filing date/month	Nov-2019
Settlement	-----
Natco's generic launch	-----
Settlement timelines	-----
US Sales, CY 2018, USD mn (IQVIA)	USD 150 mn
Competitive landscape	-----
Para-IVs	Natco, Aurobindo
Generic companies involved in patent litigations	Natco Pharma, Aurobindo pharma
DMFs	Trifluridine, Total 6 DMFs: Natco, Aurobindo, Intas Pharma, MSN Labs, Biophore India, Yuki Gosei Kogyo. Tipiracil, Total 7 DMFs: Natco, Aurobindo, Intas Pharma, MSN Labs, Biophore India, Taiho Pharma.

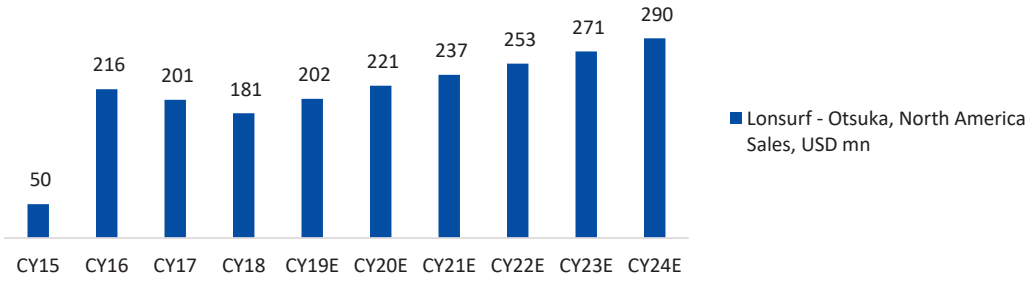
Figure-144: Trifluridine DMFs

Submit Date	Holder
11/20/2014	Yuki Gosei Kogyo Co Ltd
9/14/2018	Biophore India Pharmaceuticals Pvt Ltd
2/16/2019	Msn Laboratories Private Ltd
3/8/2019	Intas Pharmaceuticals Ltd
5/23/2019	Aurobindo Pharma Ltd
8/8/2019	Natco Pharma Ltd

Figure-145: Tipiracil DMFs

Submit Date	Holder
11/25/2014	Taiho Pharmaceutical Co Ltd
9/28/2018	Biophore India Pharmaceuticals Pvt Ltd
1/31/2019	Msn Laboratories Private Ltd
2/19/2019	Intas Pharmaceuticals Ltd
3/2/2019	Msn Laboratories Private Ltd
4/18/2019	Aurobindo Pharma Ltd
8/8/2019	Natco Pharma Ltd

Figure-146: Lonsurf / Trifluridine-Tipiracil US Sales, Otsuka (Taiho Pharma)



FOCUS CHARTS

Figure-147: Sales, growth

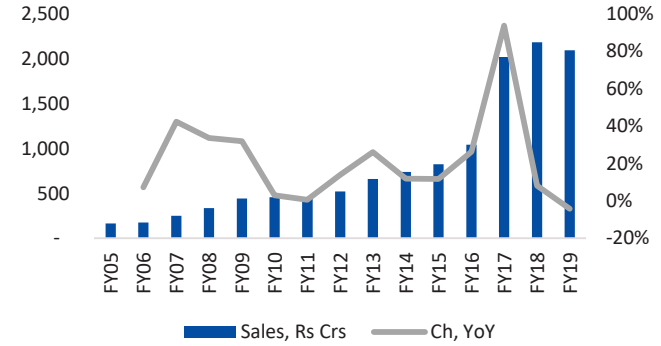


Figure-148: EBITDA, EBITDA margin

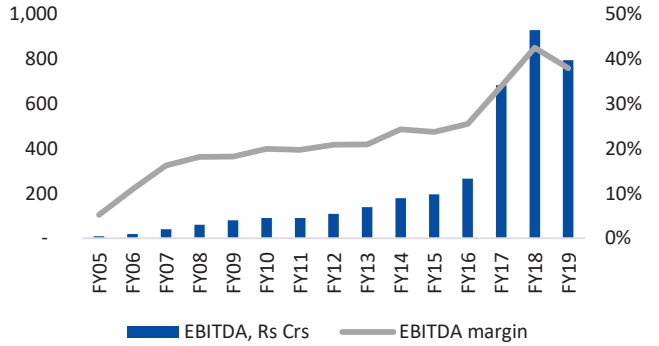


Figure-149: PAT, growth

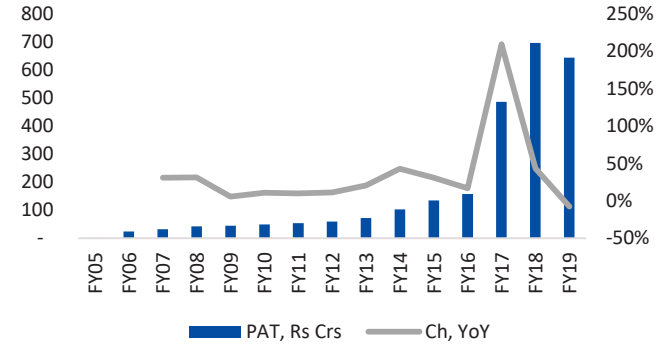


Figure-150: Gross margin

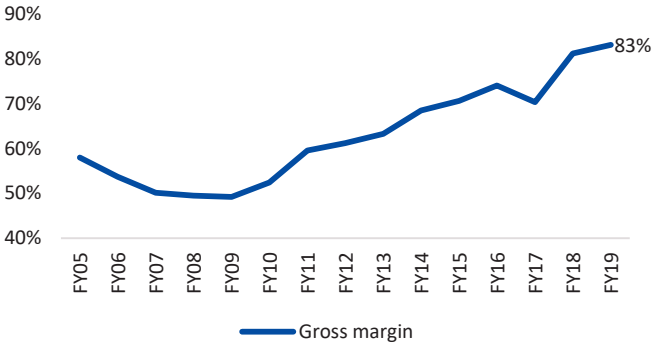


Figure-151: EBITDA margin

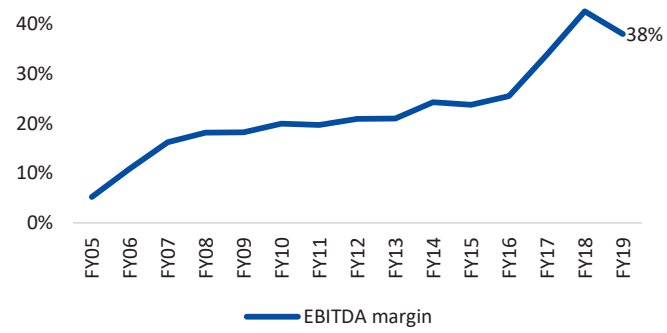


Figure-152: PAT margin

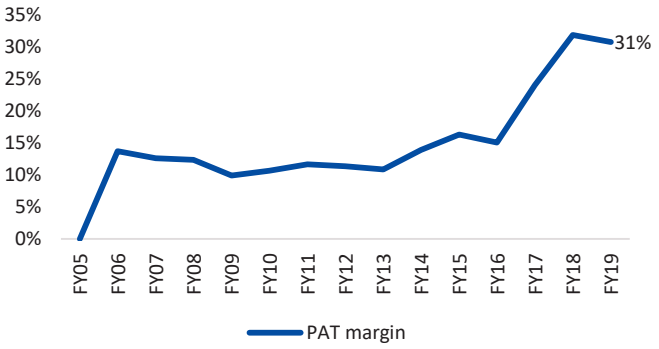


Figure-153: R&D

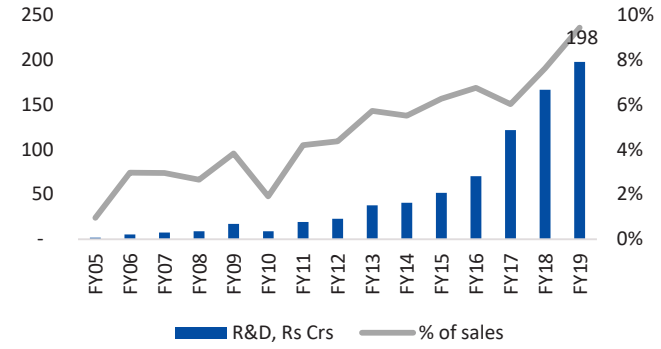


Figure-154: Legal expenses

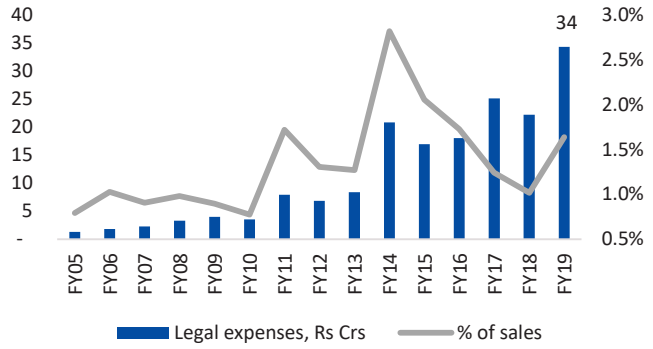


Figure-155: Interest

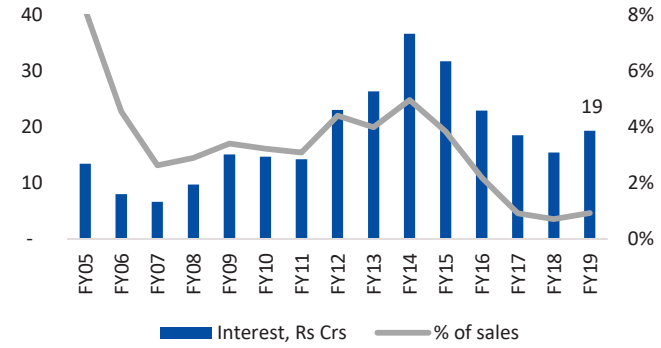


Figure-156: Interest, % of EBITDA

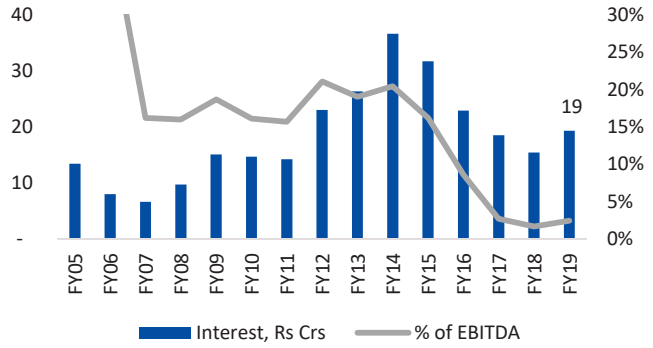


Figure-157: Debtor days

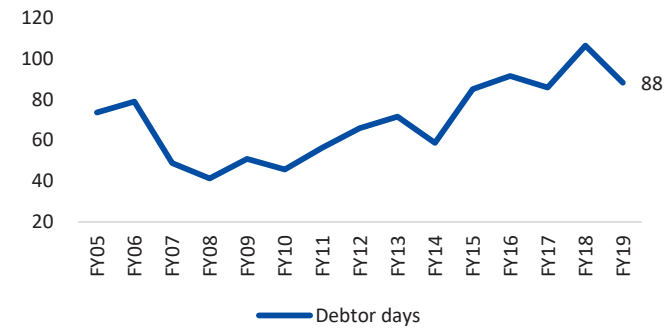


Figure-158: Inventory days

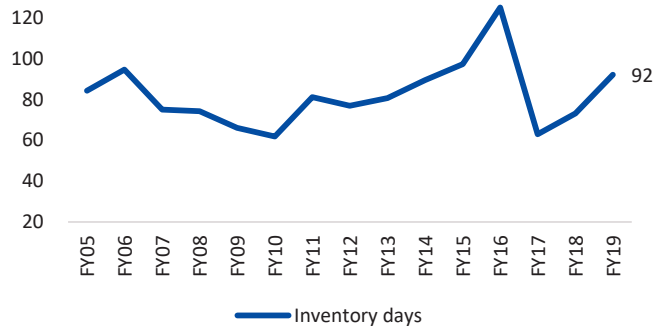


Figure-159: Creditor days

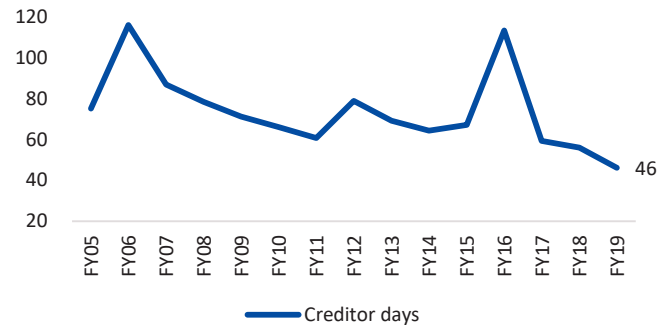


Figure-160: Working capital - days

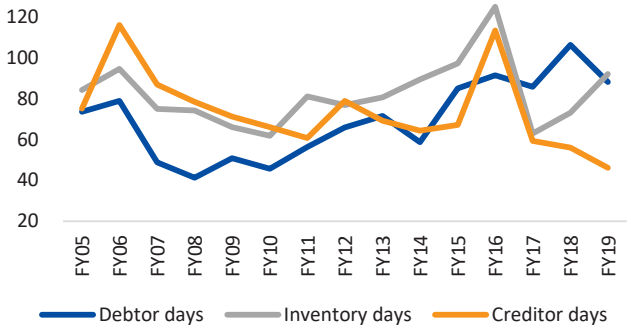


Figure-161: Net WC

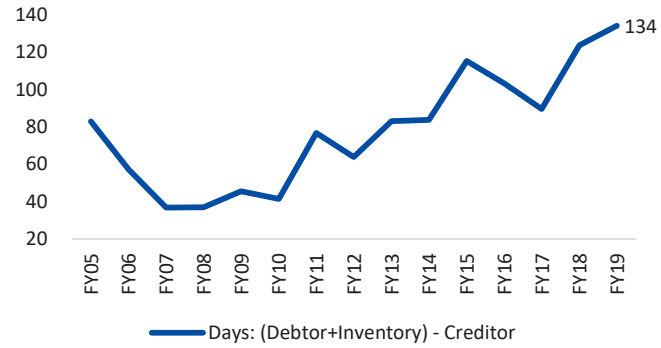


Figure-162: Net WC (% of sales)

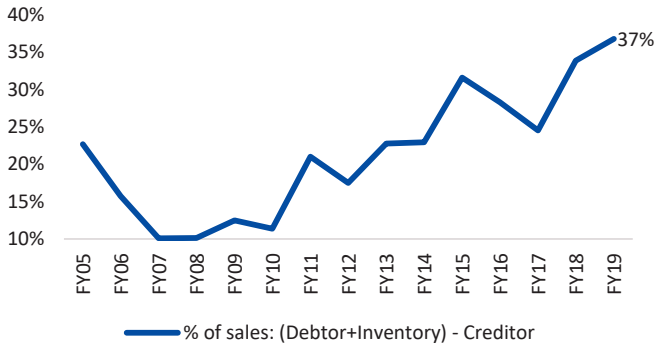


Figure-163: Gross block

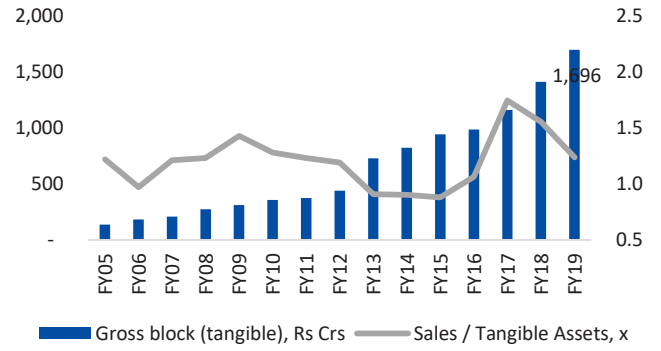


Figure-164: Gross block + CWIP

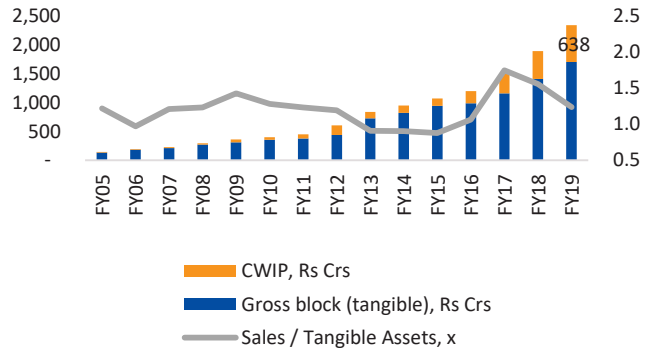


Figure-165: Net debt

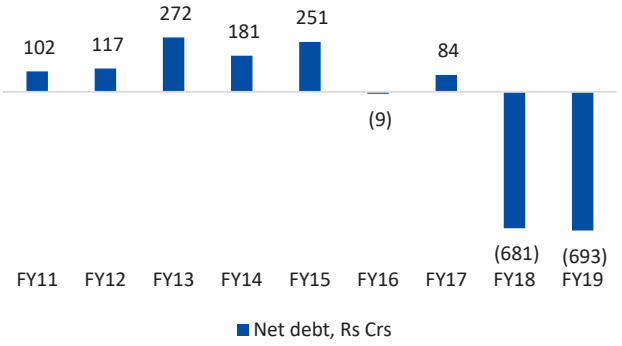


Figure-166: Net debt/EBITDA

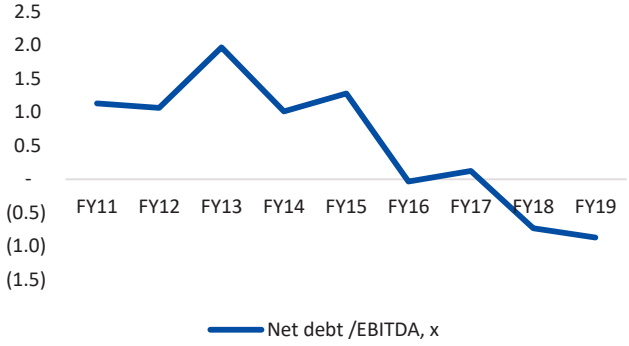


Figure-167: PAT

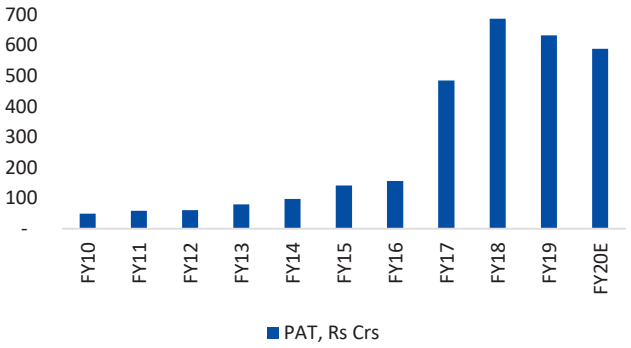


Figure-168: Stock price

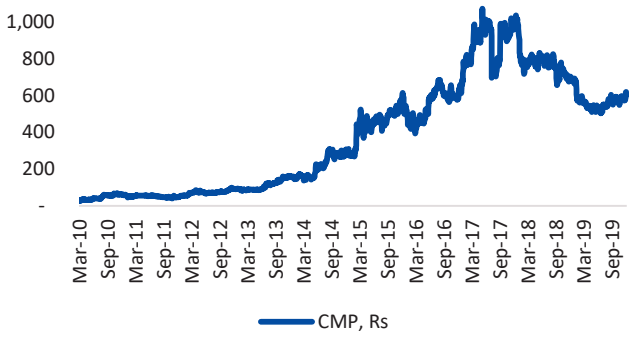


Figure-169: Gross cash flow

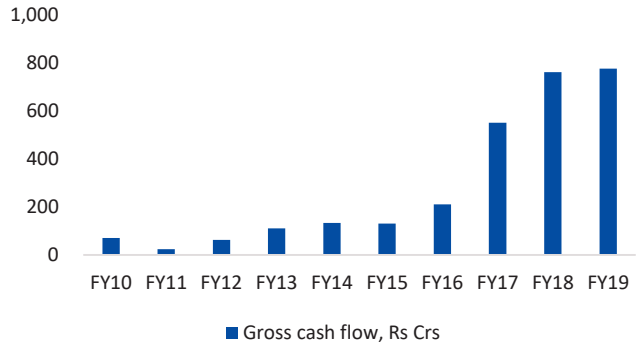


Figure-170: Investment in working capital

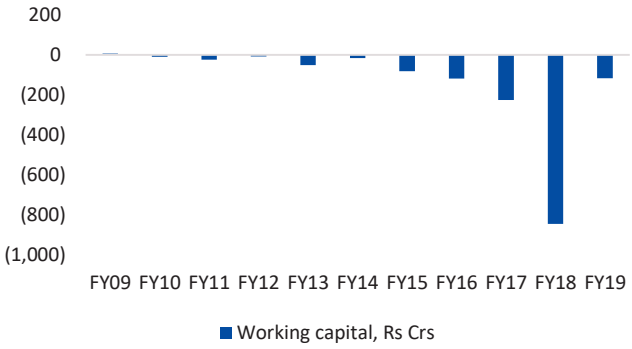


Figure-171: Operating cash flow

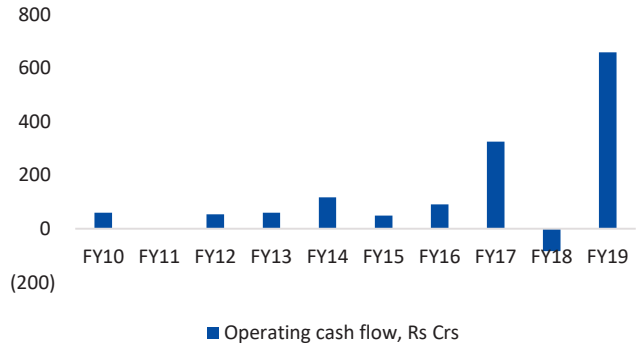


Figure-172: Capex

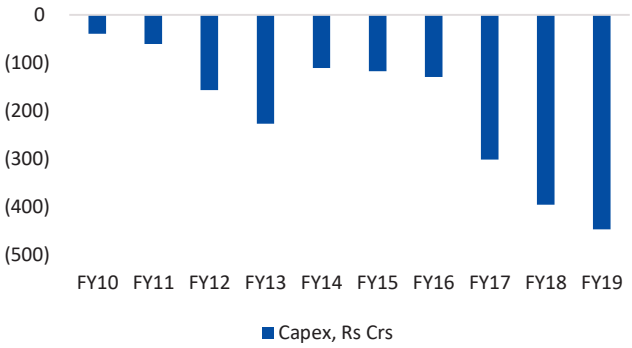


Figure-173: Free cash flow

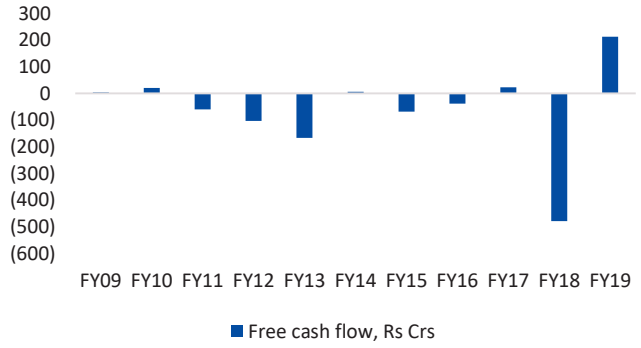


Figure-174: Cash flow

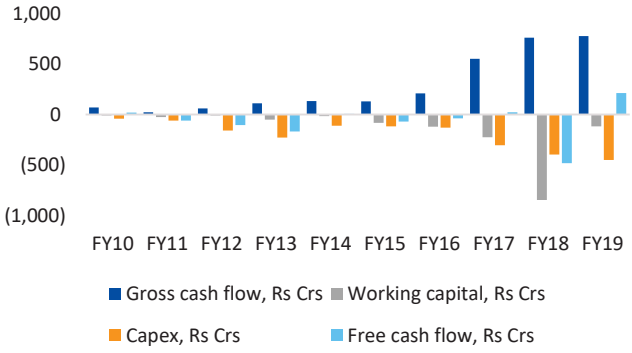


Figure-175: RoE

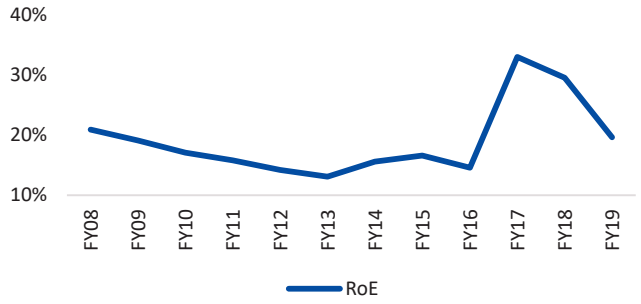
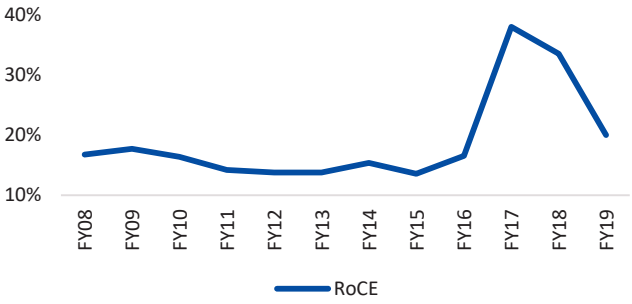
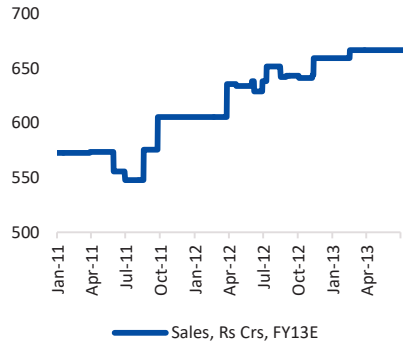


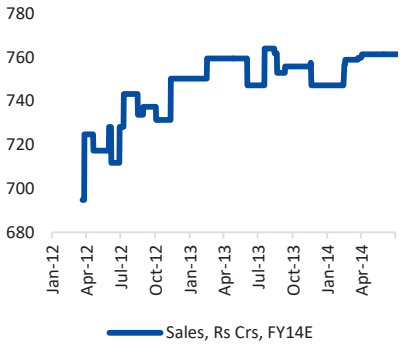
Figure-176: RoCE

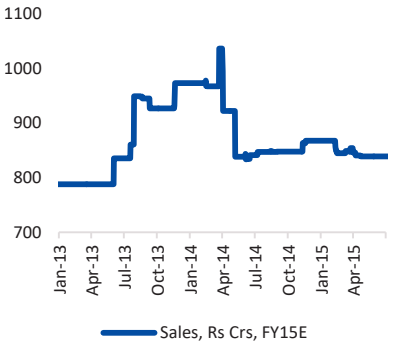


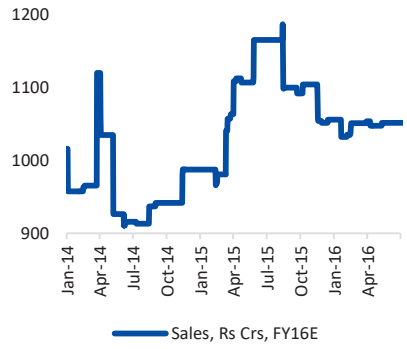
Sales Estimates – Revision

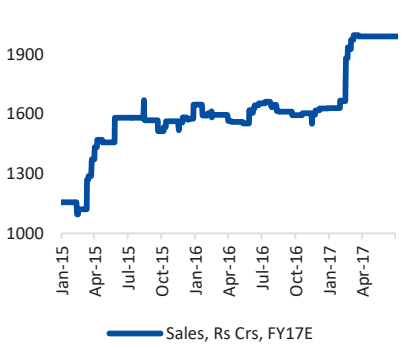
Significant downgrade in FY19 expectations. FY20 has also gone the same way.

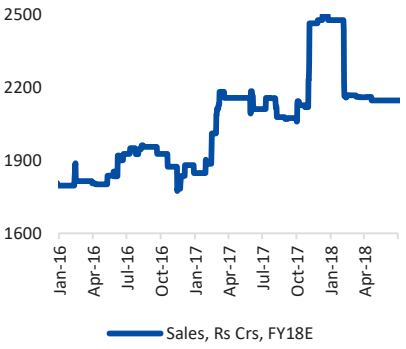


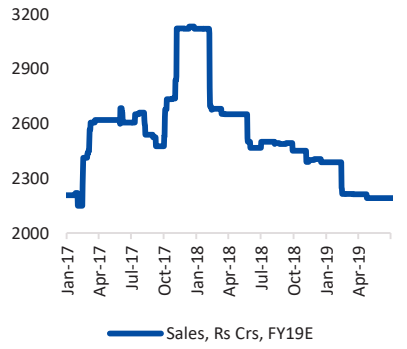


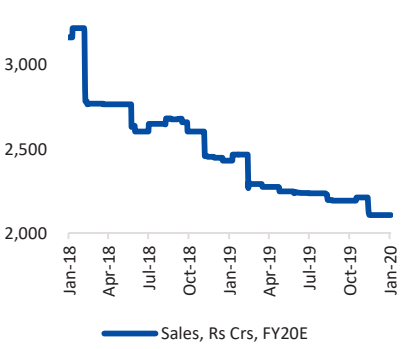


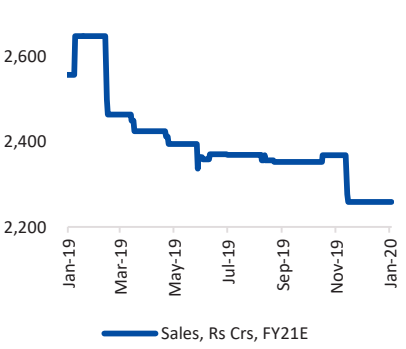




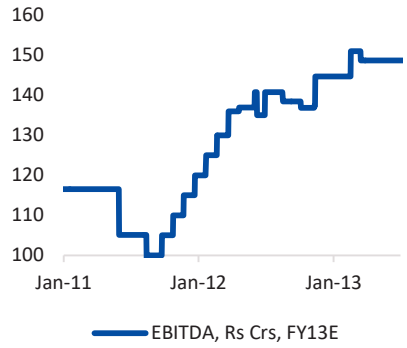


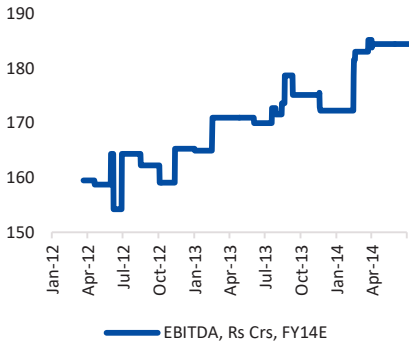


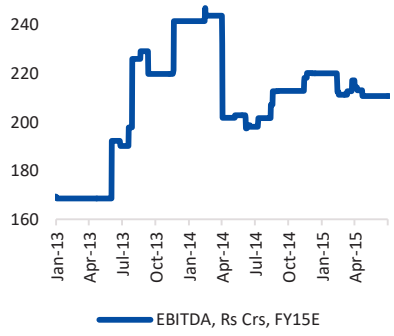


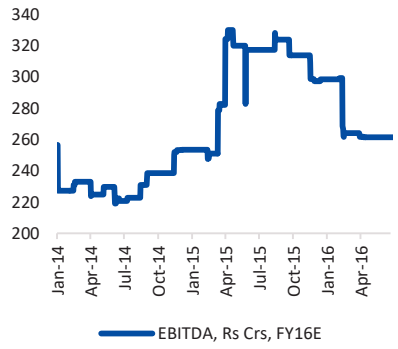


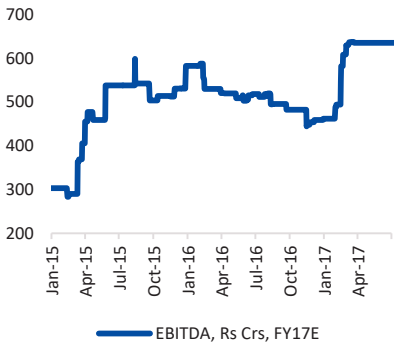
EBITDA Estimates – Revision

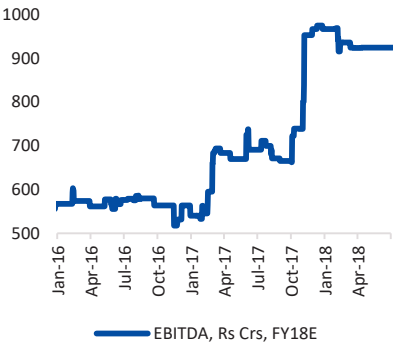


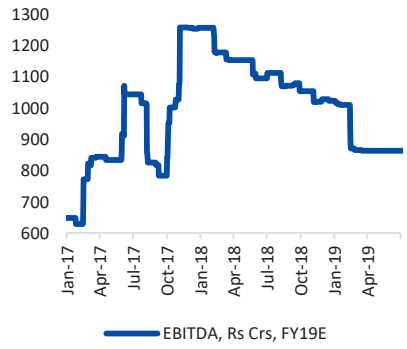


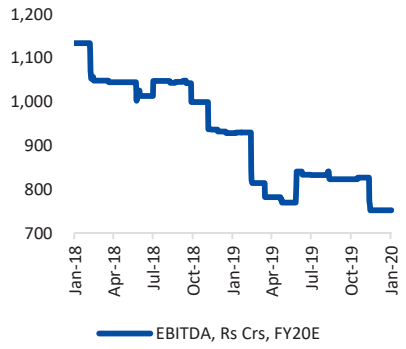


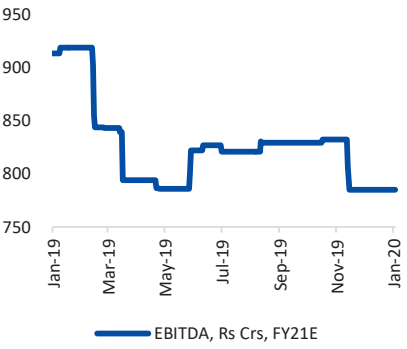




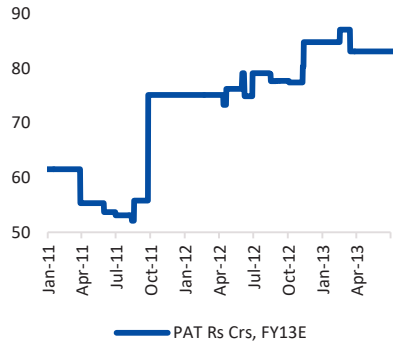


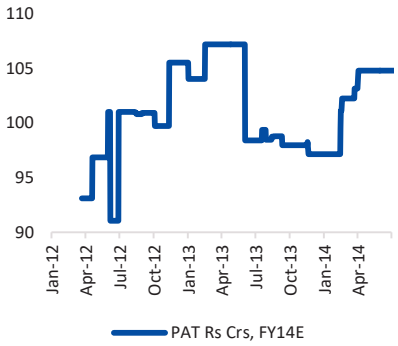


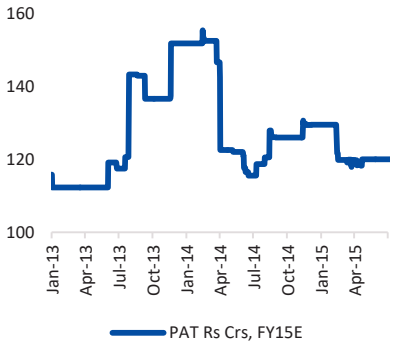


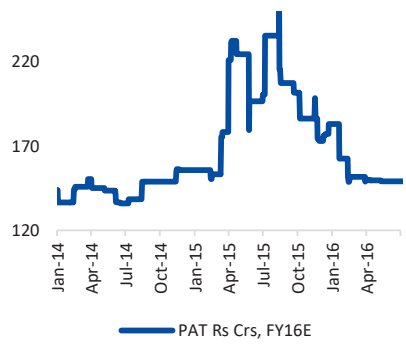


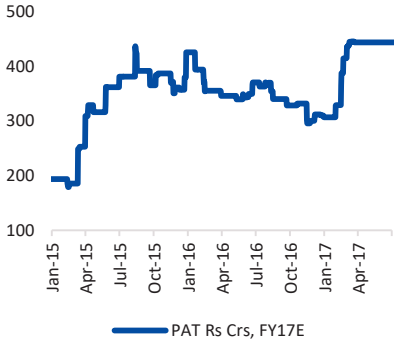
PAT Estimates – Revision

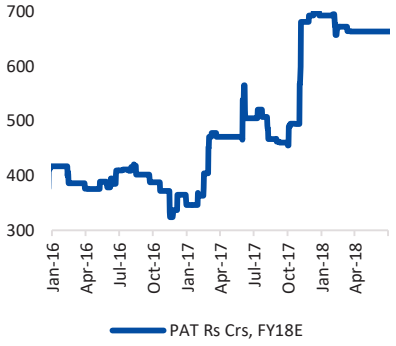


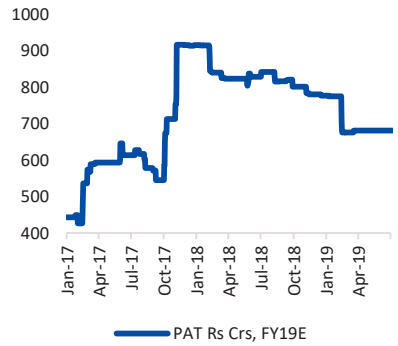


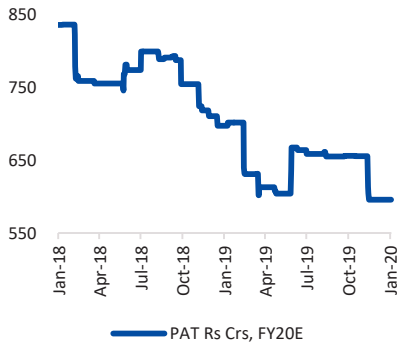


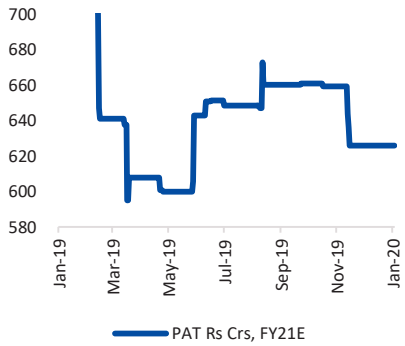












Financials

Income statement						(INR crs)
Year to March	FY14	FY15	FY16	FY17	FY18	FY19
Sales	739	825	1042	2020	2185	2095
Operating expenses	560	629	777	1337	1256	1300
EBITDA	179	196	266	683	928	795
Depreciation and amortisation	30	47	51	54	66	81
EBIT	149	149	215	629	862	714
Interest expenses	37	32	23	19	15	19
Profit before tax	129	132	204	624	887	825
Provision for tax	31	2	48	140	192	182
Core profit	98	130	156	485	695	642
Extraordinary items	-1	11	0	0	-8	-10
Profit after tax	97	141	156	485	687	632
Adjusted net profit	97	141	156	485	687	632
Equity shares outstanding (Cr)	17	17	17	17	18	18
EPS (INR) basic	6	8	9	28	37	35
Diluted shares (Cr)	17	17	17	17	18	18
EPS (INR) fully diluted	6	8	9	28	37	35
Dividend per share	1	1	0	7	8	5
Dividend payout (%)	17	13	0	24	22	14

Common size metrics- as % of net revenues						
Year to March	FY14	FY15	FY16	FY17	FY18	FY19
Operating expenses	75.7	76.3	74.5	66.2	57.5	62.1
Depreciation	4.1	5.7	4.9	2.7	3.0	3.9
Interest expenditure	5.0	3.8	2.2	0.9	0.7	0.9
EBITDA margins	24.3	23.7	25.5	33.8	42.5	37.9
Net profit margins	13.2	17.1	14.9	24.0	31.5	30.2

Growth metrics (%)						
Year to March	FY14	FY15	FY16	FY17	FY18	FY19
Revenues	11.9	11.7	26.3	93.8	8.1	(4.1)
EBITDA	29.6	9.2	35.6	157.3	35.9	(14.4)
PBT	26.0	2.2	54.6	206.5	42.1	(7.0)
Net profit	48.9	32.8	19.6	211.2	43.4	(7.6)
EPS	41.2	43.2	5.4	210.3	34.1	(7.1)

Balance sheet						(INR crs)
As on 31st March	FY14	FY15	FY16	FY17	FY18	FY19
Equity share capital	33	33	35	35	37	37
Preference Share Capital	0	0	0	0	0	0
Reserves & surplus	693	813	1,261	1,614	3,035	3,453
Shareholders funds	726	846	1,296	1,649	3,072	3,489
Secured loans	233	278	102	202	158	0
Unsecured loans	8	34	10	20	16	0
Borrowings	240	312	113	222	173	386
Minority interest	7	5	5	4	4	2
Sources of funds	**973**	**1,163**	**1,413**	**1,875**	**3,249**	**3,877**
Gross block	820	940	983	1,159	1,408	1,696
Depreciation	171	226	273	326	389	469
Net block	649	714	710	833	1,019	1,227
Capital work in progress	124	129	212	336	480	638
Total fixed assets	773	843	922	1,169	1,499	1,865
Unrealised profit	0	0	0	0	0	0
Investments	2	2	22	32	77	169
Inventories	181	220	357	349	438	529
Sundry debtors	119	192	262	475	638	506
Cash and equivalents	11	13	45	36	184	280
Loans and advances	57	57	151	195	803	884
Other current assets	0	0	0	0	0	0
Total current assets	368	483	815	1,055	2,062	2,199
Sundry creditors and others	166	198	376	390	403	327
Provisions	2	1	5	15	16	16
Total CL & provisions	167	199	381	405	419	342
Net current assets	200	284	434	651	1,644	1,856
Net Deferred tax	-43	-12	-15	-15	-14	-12
Misc expenditure	45	50	49	38	45	-1
Uses of funds	**973**	**1,163**	**1,413**	**1,875**	**3,249**	**3,877**
Book value per share (INR)	44	51	74	95	167	191

Cash flow statement

Year to March	FY14	FY15	FY16	FY17	FY18	FY19
Net profit	99	119	156	485	703	653
Add: Depreciation	30	47	51	54	66	81
Add: Misc expenses written off	5	(5)	1	11	(6)	45
Add: Deferred tax	(1)	(31)	3	0	(1)	(2)
Gross cash flow	133	131	210	551	762	777
Less: Changes in W. C.	16	81	119	226	845	117
Operating cash flow	118	49	92	325	(83)	660
Less: Capex	111	118	130	302	396	447
Free cash flow	**7**	**(68)**	**(38)**	**24**	**(479)**	**213**

Ratios

Year to March	FY14	FY15	FY16	FY17	FY18	FY19
ROAE (%)	15.6	16.6	14.5	32.9	29.4	19.6
ROACE (%)	15.3	13.6	16.5	37.9	33.5	20.0
Debtors (days)	59	85	92	86	107	88
Current ratio	2.2	2.4	2.1	2.6	4.9	6.4
Debt/Equity	0.3	0.4	0.1	0.1	0.1	0.1
Inventory (days)	89	97	125	63	73	92
Payable (days)	64	67	114	59	56	46
Cash conversion cycle (days)	84	115	103	90	124	134
Net Debt/EBITDA	1.0	1.3	0.0	0.1	-0.7	-0.9
Adjusted debt/Equity	0.3	0.4	0.1	0.1	0.0	0.0

Valuation parameters

Year to March	FY14	FY15	FY16	FY17	FY18	FY19
Diluted EPS (INR)	5.9	8.5	9.0	27.8	37.3	34.6
Y-o-Y growth (%)	*41.2*	*43.2*	*5.4*	*210.3*	*34.1*	*(7.1)*
CEPS (INR)	8	11	12	31	41	40
Diluted P/E (x)	101.1	70.6	67.0	21.6	16.1	17.3
Price/BV(x)	13.7	11.8	8.1	6.3	3.6	3.1
EV/Sales (x)	13.7	12.4	10.0	5.2	4.8	4.9
EV/EBITDA (x)	56.3	52.2	39.3	15.4	11.2	12.9
Diluted shares O/S	16.5	16.6	17.4	17.5	18.5	18.3
Basic EPS	5.9	8.5	9.0	27.8	37.3	34.6
Basic PE (x)	101.1	70.6	67.0	21.6	16.1	17.3
Dividend yield (%)	0.2	0.2	0.0	1.1	1.4	0.8

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Rating	Expected to
Buy	appreciate more than 15% over a 12-month period
Hold	appreciate between 5-15% over a 12-month period
Reduce	Return below 5% over a 12-month period

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