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PINC Quick Bite  
Sector: Pharmaceuticals  
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## COMPULSORY LICENSING

**Sushant Dalmia, CFA** +91-22-6618 6462  
sushant.dalmia@pinc.co.in  
**Poonam Sanghavi** +91-22-6618 6709  
poonam.sanghavi@pinc.co.in

### A Landmark Order

**Natco Pharma (Natco) has won the Compulsory License (CL) to manufacture and sell generic version of Bayer's Nexavar used in the treatment of advanced stage liver and kidney cancer. Natco would price the drug at Rs8,800 per month (97% discount to the innovator price) and pay 6% royalty to Bayer under the CL. The Controller of Patent has granted CL to Natco based on all the three grounds 1) Nexavar drug demand was not met by Bayer 2) Nexavar was not manufactured in India in spite getting approval in 2005 3) Nexavar was not available at a reasonably affordable price. Further, the CL was issued in spite of the fact that Cipla had entered the market with a generic product priced at 89% discount to the innovator price. Natco expects to clock sales to the tune of Rs250-300mn from the opportunity. We expect the company to generate OPM of ~20% before any royalty payments.**

While the order could be challenged by Bayer in the court of law, it paves the way for domestic pharma companies to go for CL of costlier drugs (primarily Oncology and ARV) in addition to launching the generic version of the product. On the other hand, from the innovator pharma companies' point of view, they could become more selective in launching and pricing of patented products in India.

**What is Compulsory Licensing?:** CL under the patent system is an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the State. The WTO states that CL is where a government allows the local industry to produce the patented products or process without the consent of the patent owner. CL are being issued by developed as well as developing countries even in recent times. Under Section 84 of the Patent Act at any time after expiration of three years from the date of grant of a patent any person can make an application to the controller for grant of CL on the patent on any of following grounds:

- The reasonable requirements of the public with respect to the patented invention have not been satisfied.
- The patented invention is not available to the public at a reasonably affordable price.
- The patented invention is not worked in the territory of India.

**Background of Nexavar CL:** Bayer launched the drug in 2005 for treatment of kidney cancer and received an additional approval in 2007 for liver cancer. The drug needs to be taken by the patient throughout his lifetime and the cost of therapy is Rs2,80,428/- per month and Rs3.4mn per year. Natco had approached Bayer with a voluntary license to manufacture and distribute generic Nexavar in India which was rejected by Bayer. As a result, Natco filed for an application for CL on 29<sup>th</sup> July 2011. The application for CL was filed after lapse of three years from the grant of patent. Natco under the application proposed to sell the drug at a price of Rs8,800 per month.

**Other Probable CL launches:** As per media reports Cipla has applied for voluntary licenses for Raltegravir (ARV drug) to Merck while Natco has also applied for Maraviroc (ARV drug) to Pfizer/Glaxo. In case the innovator declines the voluntary license application then the domestic companies could go for CL. Further, few of the patented drugs in India such as Nilotinib (Novartis), Sunitinib (Pfizer) and Dasatinib (BMS) could be on the domestic player's radar.

### Exhibit 1: Natco's pricing and manufacturing cost of Nexavar

Particulars	Amount (Rs)
MRP (inclusive of sales tax)	8,900
Margin to distributor, stockist and retailer (approx 30% on MRP)	2,670
Cost of manufacture of the product Nexavar	4,856
Billing price of company to distributors	6,105
Margin to the company	1,250

Source: Intellectual Property India, PINC Research; Note: The cost excludes any royalty payment to Bayer

**Exhibit 2: Nexavar demand not met**

	Total patients	Demand for 80% of patients	Bottles per month (required)	Bottles imported in 2008	Bottles imported in 2009	Bottles imported in 2010
Liver Cancer	~20,000	~16,000	~16,000	NIL	~200 bottles	Unknown
Kidney Cancer	~8,900	~7,120	~7,120			

Source: Intellectual Property India, PINC Research

**Exhibit 3: Bayer's Nexavar Sales**

	2006	2007	2008	2009	2010
Sales per year (Worldwide)	USD165mn	USD371.7mn	USD677.8mn	USD843.5mn	USD934mn
Sales in India (Rs)	NIL	NIL	NIL	160mn	Unknown

Source: Intellectual Property India, PINC Research

**T E A M**

**EQUITY DESK**

Sadanand Raje	Head - Institutional Sales Technical Analyst	<a href="mailto:sadanand.raje@pinc.co.in">sadanand.raje@pinc.co.in</a>	91-22-6618 6366
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**RESEARCH**

Vineet Hetamasaria, CFA	<b>Head of Research, Auto, Cement</b>	<a href="mailto:vineet.hetamasaria@pinc.co.in">vineet.hetamasaria@pinc.co.in</a>	91-22-6618 6388
Nikhil Deshpande	<i>Auto, Auto Ancillary, Cement</i>	<a href="mailto:nikhil.deshpande@pinc.co.in">nikhil.deshpande@pinc.co.in</a>	91-22-6618 6339
Tasmai Merchant	<i>Auto, Auto Ancillary, Cement</i>	<a href="mailto:tasmai.merchant@pinc.co.in">tasmai.merchant@pinc.co.in</a>	91-22-6618 6377
Vinod Nair	<i>Construction, Power, Capital Goods</i>	<a href="mailto:vinod.nair@pinc.co.in">vinod.nair@pinc.co.in</a>	91-22-6618 6379
Ankit Babel	<i>Capital Goods, Engineering</i>	<a href="mailto:ankit.b@pinc.co.in">ankit.b@pinc.co.in</a>	91-22-6618 6551
Hitul Gutka	<i>Power</i>	<a href="mailto:hitul.gutka@pinc.co.in">hitul.gutka@pinc.co.in</a>	91-22-6618 6410
Subramaniam Yadav	<i>Construction</i>	<a href="mailto:subramaniam.yadav@pinc.co.in">subramaniam.yadav@pinc.co.in</a>	91-22-6618 6371
Madhura Joshi	<i>Power</i>	<a href="mailto:madhura.joshi@pinc.co.in">madhura.joshi@pinc.co.in</a>	91-22-6618 6395
Satish Mishra	<i>Fertiliser, Oil &amp; Gas</i>	<a href="mailto:satish.mishra@pinc.co.in">satish.mishra@pinc.co.in</a>	91-22-6618 6488
Urvashi Biyani	<i>Fertiliser, Oil &amp; Gas</i>	<a href="mailto:urvashi.biyani@pinc.co.in">urvashi.biyani@pinc.co.in</a>	91-22-6618 6334
Naveen Trivedi	<i>FMCG</i>	<a href="mailto:naveent@pinc.co.in">naveent@pinc.co.in</a>	91-22-6618 6384
Rohit Kumar Anand	<i>IT Services</i>	<a href="mailto:rohit.anand@pinc.co.in">rohit.anand@pinc.co.in</a>	91-22-6618 6372
Niraj Garhyan	<i>IT Services</i>	<a href="mailto:niraj.garhyan@pinc.co.in">niraj.garhyan@pinc.co.in</a>	91-22-6618 6382
Namrata Sharma	<i>Media</i>	<a href="mailto:namrata.sharma@pinc.co.in">namrata.sharma@pinc.co.in</a>	91-22-6618 6412
Sakshee Chhabra	<i>Media</i>	<a href="mailto:sakshee.chhabra@pinc.co.in">sakshee.chhabra@pinc.co.in</a>	91-22-6618 6516
Bikash Bhalotia	<i>Metals, Mining</i>	<a href="mailto:bikash.bhalotia@pinc.co.in">bikash.bhalotia@pinc.co.in</a>	91-22-6618 6387
Harleen Babber	<i>Metals, Mining</i>	<a href="mailto:harleen.babber@pinc.co.in">harleen.babber@pinc.co.in</a>	91-22-6618 6389
Dipti Vijaywargi	<i>Metals, Mining</i>	<a href="mailto:dipti.vijaywargi@pinc.co.in">dipti.vijaywargi@pinc.co.in</a>	91-22-6618 6393
Sushant Dalmia, CFA	<i>Pharma</i>	<a href="mailto:sushant.dalmia@pinc.co.in">sushant.dalmia@pinc.co.in</a>	91-22-6618 6462
Poonam Sanghavi	<i>Pharma</i>	<a href="mailto:poonam.sanghavi@pinc.co.in">poonam.sanghavi@pinc.co.in</a>	91-22-6618 6709
Suman Memani	<i>Real Estate, Mid caps</i>	<a href="mailto:suman.memani@pinc.co.in">suman.memani@pinc.co.in</a>	91-22-6618 6479
Abhishek Kumar	<i>Real Estate, Mid caps</i>	<a href="mailto:abhishek.kumar@pinc.co.in">abhishek.kumar@pinc.co.in</a>	91-22-6618 6398
C Krishnamurthy	<i>Technical Analyst</i>	<a href="mailto:krishnamurthy.c@pinc.co.in">krishnamurthy.c@pinc.co.in</a>	91-22-6618 6747

**SALES**

Rajeev Gupta	<i>Equities</i>	<a href="mailto:rajeev.gupta@pinc.co.in">rajeev.gupta@pinc.co.in</a>	91-22-6618 6486
Ankur Varman	<i>Equities</i>	<a href="mailto:ankur.varman@pinc.co.in">ankur.varman@pinc.co.in</a>	91-22-6618 6380
Himanshu Varia	<i>Equities</i>	<a href="mailto:himanshu.varia@pinc.co.in">himanshu.varia@pinc.co.in</a>	91-22-6618 6342
Shailesh Kadam	<i>Derivatives</i>	<a href="mailto:shaileshk@pinc.co.in">shaileshk@pinc.co.in</a>	91-22-6618 6349
Ganesh Gokhale	<i>Derivatives</i>	<a href="mailto:ganeshg@pinc.co.in">ganeshg@pinc.co.in</a>	91-22-6618 6347

**DEALING**

Amar Margaje		<a href="mailto:amar.margaje@pinc.co.in">amar.margaje@pinc.co.in</a>	91-22-6618 6327
Ashok Savla		<a href="mailto:ashok.savla@pinc.co.in">ashok.savla@pinc.co.in</a>	91-22-6618 6321
Sajjid Lala		<a href="mailto:sajjid.lala@pinc.co.in">sajjid.lala@pinc.co.in</a>	91-22-6618 6337
Raju Bhavsar		<a href="mailto:rajub@pinc.co.in">rajub@pinc.co.in</a>	91-22-6618 6322
Hasmukh D. Prajapati		<a href="mailto:hasmukhp@pinc.co.in">hasmukhp@pinc.co.in</a>	91-22-6618 6325
Dhirenpuri D. Goswami		<a href="mailto:dhirenpurig@pinc.co.in">dhirenpurig@pinc.co.in</a>	91-22-6618 6345
Arjun Prajapati		<a href="mailto:arjun.prajapati@pinc.co.in">arjun.prajapati@pinc.co.in</a>	91-22-6618 6346

**DIRECTORS**

Gaurang Gandhi		<a href="mailto:gaurangg@pinc.co.in">gaurangg@pinc.co.in</a>	91-22-6618 6400
Hemang Gandhi		<a href="mailto:hemangg@pinc.co.in">hemangg@pinc.co.in</a>	91-22-6618 6400
Ketan Gandhi		<a href="mailto:ketang@pinc.co.in">ketang@pinc.co.in</a>	91-22-6618 6400

**COMPLIANCE**

Rakesh Bhatia	Head Compliance	<a href="mailto:rakeshb@pinc.co.in">rakeshb@pinc.co.in</a>	91-22-6618 6400
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Rating Objective		
Rating	Large Caps	Mid Caps
	M.Cap > USD1bn	M.Cap <= USD1bn
Return %		
<b>BUY</b>	<b>More than 15</b>	<b>More than 20</b>
<b>Accumulate</b>	<b>5 to 15</b>	<b>10 to 20</b>
<b>Reduce</b>	<b>(-)5 to +5</b>	<b>0 to 10</b>
<b>Sell</b>	<b>Below (-)5</b>	<b>Less than 0</b>

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Member : Bombay Stock Exchange & National Stock Exchange of India Ltd. : Sebi Reg No: INB 010989331. Clearing No : 211  
1216, Maker Chambers V, Nariman Point, Mumbai - 400 021; Tel.: 91-22-66186633/6400 Fax : 91-22-22049195

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