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Food For Thought

Biosimilars - The Next Generic Honeypot

Global & Indian generic Pharma companies now focusing on biogenerics/biosimilars space…

Currently, Sandoz & Teva are the best placed Global Pharma companies...

Biocon & DRL are currently the most well positioned Indian Pharma companies…

May 31, 2011

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Research Contact: *Associate Director, Research: Hitesh Kuvelkar Mob. +91 9833 732633*
Email: hitesh.kuvelkar@fglobal.com

Sales Offices: *India Sales: Tel. No: +91-22-400 12 440 Email: indiasales@fglobal.com*
fgasiasales@bloomberg.net

UK, US & Europe: Tel.: + 44-203-189 0057 Email: uk@fglobal.com

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The Story…

Apart from the global generic players, such as Sandoz, Teva Pharmaceutical Industries Ltd (TEVA) and Hospira (HSP), even the Indian generic players, like DRL, Biocon, Wockhardt and Intas are making huge investments in order to ride the huge biogenerics wave that is set to begin mainly from 2014 onwards

In one of our earlier reports on Biosimilars (please refer to First Global's, '*Pharmaceuticals: Food For Thought: Biosimilars - The Next Generic Honeypot'*, dated December 10, 2010, we had discussed the next big biogenerics opportunity that is likely to open up for Generic Pharma companies. Apart from the global generic players, such as Sandoz, Teva Pharmaceutical Industries Ltd (TEVA) and Hospira (HSP), even the Indian generic players, like DRL, Biocon, Wockhardt and Intas are making huge investments in order to ride the huge biogenerics wave that is set to begin mainly from 2014 onwards.

In this report, we have delved into the myths and facts related to biosimilars. As mentioned in our earlier report, the biogenerics/biosimilars opportunity that is opening up is undoubtedly quite huge, since the size of the biosimilars market is likely to increase from the current $380 mn to about $3.7 bn by 2015, with over 30 branded biologicals having sales of $51 bn scheduled to lose their patent exclusivity between 2011 and 2015. Not surprisingly, more and more companies are entering the biosimilars race, though the competition is likely to be limited due to the complexities involved in this space. Among the global Pharma companies, Sandoz was one of the early entrants in this segment, followed by other global generic players, such as Teva and Hospira, which are entering this space. In view of this huge upcoming opportunity, even Global branded Pharma companies, such as Merck & Co (MRK) and Pfizer Inc. (PFE), have recently begun tapping the biosimilars market through partnerships, with Pfizer entering into a partnership with Biocon in October 2010 and Merck partnering with Parexel (US based contract research provider) in January 2011. From the Indian prospective, generic companies, such as Biocon, DRL and Wockhardt, were the early entrants in the biosimilars space, while other players, like Cipla, are gradually making inroads into this segment though various investments. Moreover, even Global Biotech companies, like Biogen Idec (BIIB), are also setting up a biosimilars division, along with carrying out indigenous work on biotech products, in order to achieve maximum capacity utilisation. Thus, the race to capitalize on the huge biosimilars opportunity has begun. However, we believe that foraying into the biosimilars market is likely to be much tougher in comparison to entering the Pharma generics space, as there exist a number of hurdles in the biosimilars segment, such as stringent approval procedures, extensive international clinical trials required to prove the bioequivalence of a product and strong marketing capabilities to promote a product after it receives approval. Though, the competitive landscape for biosimilars is likely to be less tough, there are still questions surrounding its acceptance. To our mind, achieving market share gains in the biosimilars space is likely to be a tough task, thus raising concerns over the lengthy gestation period and return on investments. Hence, a number of global as well as Indian Pharma players are making a cautious and gradual entry into the biosimilars market and are weighing the pros and cons before making any big investments in this space. Also, a number of companies entering the biosimilars space are attempting the partnership model and are scouting for partners to commercialise these products.

Thus, the race to capitalize on the huge biosimilars opportunity has begun. However, we believe that foraying into the biosimilars market is likely to be much tougher in comparison to entering the Pharma generics space, as there exist a number of hurdles in the biosimilars segment, such as stringent approval procedures, extensive international clinical trials required to prove the bioequivalence of a product and strong marketing capabilities to promote a product after it receives approval

Thus, amidst the concerns and hurdles in the biosimilars space, the key question that now arises is who are the players that are likely to benefit the most from this huge upcoming opportunity. To our mind, currently Sandoz, the generics subsidiary of Novartis AG (NOVN), appears best positioned to grab the biggest chunk of the biogenerics honey pot, due to the company's strong pipeline, as well as R&D and marketing capabilities. Sandoz was also the first company to launch a biosimilar in the US as well as in Europe, which clearly indicates the company's expertise and ability to meet the regulatory requirements associated with biosimilars. Teva appears to be the second best positioned company to benefit from the biosimilars opportunity. Other players, such as Hospira, are also gradually following suit. On home ground, Biocon appears to be the best positioned company to benefit from the huge biosimilars opportunity, considering the company's robust pipeline, strong fermentation capabilities, partnership with Pfizer, huge investments made in this segment and its partnership model being set up for entering various markets. DRL appears to be the second best positioned player to benefit from the biosimilars opportunity, in view of the company's robust pipeline, strong marketing and R&D capabilities and a good backward integrated system in place, in terms of its well equipped scientific muscle in the US to cater to biosimilars R&D and clinical research. Other players, such as Wockhardt and Intas, have also made a good entry into this space, though we believe that they still have a long way to go.

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…on home ground, Biocon appears to be the best positioned company to benefit from the huge biosimilars opportunity, considering the company's robust pipeline, strong fermentation capabilities, partnership with Pfizer, huge investments made in this segment and its partnership model being set up for entering various markets

Read on for details…

Some Facts & Myths about Biosimilars

The biosimilars opportunity is obviously quite large, though much of it lies in the US market and unfortunately, the regulatory guidelines for approval of biosimilars in the US are yet to be released. Thus, currently the overall biosimilars market is quite small; with revenue of just about $380 mn by the end of CY10 and the market is yet to open up.

However, in view of the upcoming biosimilars opportunity, a number of generic and branded Pharma companies have made biosimilars their priority in order to drive their overall growth, including Novartis, through its generic subsidiary, Sandoz, Teva, Hospira, Merck and Pfizer. However, on account of the complexities, costs and development risks involved in biosimilars, we believe that the competitive landscape for biosimilars will be limited to 'only a handful of established generic Pharma companies.

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Huge opportunity lies ahead…

Based on market data and various company reports, the global biosimilars market was worth about $380 mn in CY10. Between 2011 and 2015, patents on over 30 branded biological, with sales of $51 bn scheduled to lose patent exclusivity and the biosimilars versions of these important medicines are already under development. In 2009, the combined biosimilars market size of the US and five major European markets stood at merely $150 mn. According to various estimates, the global biosimilars market will grow from $380 mn in 2010 to $3.7 bn in 2015, as over 30 branded biologicals with sales of $51 bn will lose patent exclusivity between 2011 and 2015.

Among Global biotech products in the market, Genentech's Avastin topped the list, with worldwide sales of $7.6 bn (CHF 6.5 bn), followed by its Rituxan ($7.5 bn/CHF 6.4 bn) and Abbott's Humira ($635 bn), Amgen's Enbrel, Genentech's Herceptin ($6.4 bn), JNJ's Remicade ($4.6 bn) and Amgen's Neulasta ($3.6 bn). These blockbuster biotech drugs are likely be the next biosimilars targets.

Top selling Biotech products

Product	Company	Sales in local currency	Sales in CY10
Avastin	Roche/Genentech	CHF 6.46 bn	$7.6 bn
Rituxan/MabThera	Roche/Genentech	CHF 6.4 bn	$7.5 bn
Humira	Abbott		$6.5 bn
Enbrel	Amgen		$6.4 bn
Herceptin	Roche/Genentech	CHF 5.4 bn	$6.4 bn
Remicade	JNJ		$4.6 bn
Neulasta	Amgen		$3.6 bn
Aranesp	Amgen		$2.5 bn
Prevnar/Prevnar 13	PFE/WYE		$2.4 bn

Biotech drugs are the most expensive medications and can cost patients, their employers or insurers tens of thousands of dollars a year for just one medicine. Since biotech drugs are derived from living cells and are more complex to make, the new health laws require lengthy clinical trials before they are launched and hence could witness regulatory delays in receiving approval in the US. The US FDA has said it is working on framing guidelines on how the approval process will work and are expected by the end of the year. However, with the regulatory guidelines for the approval of biosimilars well in place in Europe and various biosimilars already available in the European market, consumers in Europe have already been enjoying savings of 20-30% for several years now.

For instance, Hospira sells Retacrit, a biogeneric version of Epogen, in Europe to patients with renal dysfunction who have anemia. Hospira does not disclose a price for Retacrit, which is sold at a 20-30% discount to the innovator's product. And Hospira is now keenly awaiting its US approval and the company is already carrying out the necessary clinical trials of its biosimilars version of Epogen in 20 US haemodialysis centres, as well as holding discussions with the FDA to prepare for the next phase of the program.

Monoclonal antibodies are currently being perceived by many to be a bigger challenge for biosimilars development than the first generation biotech drugs, such as generic epoetin, G_GSF, growth hormones, etc, particularly in view of their size and some of these monoclonal antibodies are likely to face patent expiry in the 2014 to 2016 period. In 2009, the global market for monoclonal antibodies was valued at $36 bn and is expected to increase to $64 bn in 2015. Five monoclonal antibodies account for about 75% of the total monoclonal antibody sales and they include Roche's Avastin, Herceptin, Remicade, Rituxan and Abbott's arthritis drug, Humira, with each recording annual sales of at least $4 bn. No generic monoclonal antibodies have yet been approved either in Europe or in the US and with the guidelines for these biosimilars being framed; the generic versions of these antibodies are likely to enter the markets between 2014 and 2016.

Hurdles to entering biogenerics space

The biosimilars opportunity is quite huge and attractive and hence, branded companies as well as generic Pharma companies are tapping this space. ***However, to our mind, unlike generics of chemical entities, biosimilars have their associated complexities and hurdles:***

1. ***Regulatory hurdles***
2. ***Need to carry out extensive clinical trials for obtaining approval***
3. ***Strong marketing capabilities required to improve acceptability of approved products***

1. Regulatory hurdles: Lack of guidance for implementation of biosimilars pathway in US…

The regulatory guidelines for the approval of biosimilars for the EU market are already in place and hence, the EU market for biosimilars opened up way back in 2006 itself. However, the US guidelines for their approval are yet to be released, in spite of a large percentage of the overall global biotech sales coming from the US.

US markets account for a large percentage of the overall biologics sales

Biotech product	% of sales from the US
Erythropoietin	69%
G-CSF	63%
Interferon alpha	35%
Interferon beta	55%
Human Growth hormone	33%

However, US regulators are expected to release guidelines by the end of the year due to ongoing pressure in the US to bring down the overall healthcare costs. In developing markets, such as the EU, the need for biologicals at affordable prices has led to the set up of the necessary guidelines for the approval of biosimilars much earlier and hence the EU markets have a number of approved biosimilars.

The legislation in Europe in 2004 created a legal pathway for the approval of biosimilars and hence, the first biosimilar, Omnitrope (somatropin) was approved by the European Medicines Agency (EMA) was available in Europe in 2006. The US has been a bit of a laggard, with a legal pathway being approved only in March 2010 and with practical guidance from the FDA still awaited. The EU already has general guidelines for biosimilars covering principles and biotechnology derived proteins, as well as quality and safety/efficacy guidelines. Product class specific guidelines are also in place covering human insulin, somatropin, human growth hormone, erythropoietins, interferon-alpha and low molecular weight heparins. The EMA is also currently working on concept papers/draft guidelines for a number of other product class specific guidelines, including monoclonal antibodies, interferon-beta and follicle stimulation hormone.

Due to the success of the EU's approach towards biosimilars, the USFDA has been urged to adopt a similar method for the approval of biosimilars in the US. However, it is believed that the US FDA is unlikely to adopt the EU's biosimilars guidelines, despite the fact that it could save time and resources, thus leaving the FDA to concentrate on inter-changeability. Currently, the 505 (b) 2 route is being used by players attempting to seek the approval of biosimilars, though approvals are still awaited.

Thus, in the US, the regulatory guidelines for the approval of biosimilars are still not yet in place and the USFDA is likely to further increase the hurdles by imposing huge fees for approval of biosimilars, thus indicating that developing biosimilars will be neither cheap nor easy. According to the FDA, it plans to charge the same user fees for a biosimilars application as it does for any other new biologic that comes its way. The FDA is planning on assessing those charges early on in the development process, as regulators and developers blaze a regulatory trail with the first generation of pioneering projects. The FDA expects to charge $150,000 a year during development and then subtract the total from the final tally for an approval.

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2. Need to carry out extensive clinical trials for obtaining approval

Generic versions of Pharmaceuticals or chemical entities are easy to replicate and are eventually sold at one-tenth the price of the branded product. However, Generic biotech drugs/ biosimilars are much more complex and are expected to sell at a discount of merely 10-20% to the original product, due to the need for much more extensive clinical trials on these products.

For instance, Biocon has been working on recombinant human insulin and planned to launch the product in the EU markets in FY11. However, its launch has been delayed to FY13-14, as the company is carrying out extensive clinical trials on the product in Europe. Biocon believes that once this data is available, the approval and overall acceptability for biosimilars is likely to improve. Hence, unlike Pharma generics, there is a need to carry out extensive trials on biosimilars in order to prove its bioequivalence to the originator's product.

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3. Strong marketing capabilities required to improve acceptability of approved products

A number of players desire a piece of the US market for generic versions of complex biotech drugs, but apart from the need to carry out extensive clinical trials, the winners will also need strong marketing capabilities, unlike plain generics, which does not require a strong marketing network.

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Unlike Pharmagenerics, physicians are definitely likely to be cautious about the relative safety and efficacy of biosimilars at least in the short term and hence, high promotional investment will be required. Generics players without any experience in marketing their products will need to build a sales team, either fully in-house, using a contract sales force or both, or partner with a bigger pharmaceutical or generic company. The overall acceptability of biosimilars is quite slow, which is evident from the fact that a player like Sandoz has been able to record sales of just $185 mn from biosimilars after a span of five years, in spite of having strong marketing capabilities and enjoying the first mover advantage. Hence, in view of the concern over the acceptability of biosimilars, there is a need to develop a strong marketing base in order to improve a product's overall acceptability.

Global biotech companies entering biosimilars space

Apart from generics and branded Pharma companies, even pure Biotech companies, such as Biogen, plan to simultaneously have a biosimilars division. Biogen is in discussions with several companies for forming a partnership to develop generic versions of biotech drugs and expects the biosimilars business to generate annual sales in north of $1 bn. Biogen's goal is to leverage the company's manufacturing capability without getting involved in sales and marketing. According to management, it hopes that Biogen will be responsible for manufacturing the drugs, as it has facilities in the US and Europe, while its partner will handle the clinical trials, commercialization, sales and marketing. Biogen has already started developing some biosimilars, though it has not disclosed any details.

The Financial Implications

Huge question mark over margins in biosimilars

As biosimilars are quite complex, unlike chemical entities, the competitive pressure in this space is likely to be limited. However, there is a huge question mark over the acceptability of biosimilars and the ability of the players to gain market share. This is evident from the fact that a player like Sandoz has been able to record sales of just $185 mn from biosimilars after a span of five years, in spite of having strong marketing capabilities and enjoying the first mover advantage. According to the company, the initial acceptability of biosimilars is slower, but picks up gradually. Moreover, the acceptability and market share gains in biosimilars depends upon the complexity of the product.

As biosimilars are quite complex, unlike chemical entities, the competitive pressure in this space is likely to be limited. However, there is a huge question mark over the acceptability of biosimilars and the ability of the players to gain market share

According to Sandoz's management, the acceptability of biosimilars is slower in the initial stages, though the market share gains are quite rapid once physicians gain confidence in the product, as they offer comparable better quality, safety and efficacy at more affordable prices. Price erosion and other market dynamics vary considerably by product and market. For instance, sales of Omnitrope doubled in the US in 2010 (IMS figures) and Sandoz also reached approximately 10% of total EU patient share (over 30% of new patients). In fact, Zarzio, the third biosimilar from Sandoz, is currently growing the fastest among all its three products and has even overtaken the reference product, Neupogen in both the UK and Sweden (market share of well over 40% in Sweden).

As the competition is likely to be limited, the price erosion, post patent expiry, is expected to be not more than 20-30%, though the peak market share is also unlikely to exceed 25-30%, as the acceptability of biosimilars may not be very smooth. Plus, the development costs will be significantly higher for biosimilars in comparison to chemical-based generics. Moreover, biosimilars involve the requirement of strong marketing capabilities, as well as the need to carry out extensive clinical trials in order to prove their efficacy and bioequivalence. It has been estimated that developing a biosimilar for the highly regulated markets, such as the EU and US, costs between $75-250 mn, which could also limit the number of entrants in this space. Moreover, in a move that will further increase the hurdles for approval; the USFDA appears to be planning to impose a fee for seeking the approval of biosimilars. Thus, taking into account these expenses, as well as the higher production, R&D and SG&A expenses, it still remains to be seen as to what margins can be actually earned in the biosimilars space.

In a move that will further increase the hurdles for approval, the USFDA appears to be planning to impose a fee for seeking the approval of biosimilars. Thus, taking into account these expenses, as well as the higher production, R&D and SG&A expenses, it still remains to be seen as to what margins can be actually earned in the biosimilars space

Return on investments & long gestation period a concern

As mentioned above, the likely margins to be enjoyed on biosimilars would be difficult to estimate, considering the higher development costs, requirement of extensive clinical trials, strong marketing capabilities and concern over ability to gain a respectable market share. Moreover, the probability of a successful biosimilars launch could be lower in view of the product complexities involved, thereby putting the huge R&D investments at risk. Apart from setting up fermenters, the other prime variable costs incurred in biosimilars are towards solvents and nutrients for preparation of biosimilars and the prices of these solvents are based on oil prices. Plus, biosimilars involve the need for a strong R&D set up, as well as the need to carry out extensive trials internationally. Also, Biopharmaceuticals are less stable than chemical based pharmaceuticals and hence, require cold chain distribution and have a shorter shelf life. Moreover, the supply chain for biosimilars will be very different in comparison to the current range of generic drugs, leading to an increase in the costs and complexity of distribution. Thus, huge investment requirements have restricted the entry of various generic Pharma players in the biosimilars market. Hence, there is a big question mark over the return of investment and companies, such as DRL, have been quite cautious in investing in this segment. On account of the above mentioned concerns, the entry barriers in biosimilars are higher, thereby limiting the competition.

The probability of a successful biosimilars launch could be lower in view of the product complexities involved, thereby putting the huge R&D investments at risk. Apart from setting up fermenters, the other prime variable costs incurred in biosimilars are towards solvents and nutrients for preparation of biosimilars and the prices of these solvents are based on oil prices. Plus, biosimilars involve the need for a strong R&D set up, as well as the need to carry out extensive trials internationally

Indian players, such as DRL and Biocon, entered the biosimilars space in 1999-2000 itself and both the companies focus on different areas in the segment.

Key Global and Indian players in the Biosimilars space

Sandoz, generic subsidiary of Novartis, currently enjoys about 50% of share in global biosimilars market

Sandoz, the generic subsidiary of Novartis, was the first company that managed to launch a biosimilars both in the EU as well as US markets. In April 2006, the EMEA approved the first biosimilars, Sandoz's human growth hormone, Omnitrope (somatropin). Subsequently, Sandoz received US approval for the same product and carried out its US launch in May 2006 itself. Since then, there have been no biosimilars approvals. It was only in July 2010 that the second biosimilars received approval and a number of approvals are now expected, going forward.

Sandoz generated global biosimilars sales of $185 mn in CY10, accounting for 50% of the global biosimilars market. After the launch of Omnitrope in 2006, Sandoz has been able to launch two other biosimilars, thus clearly indicating that seeking approval for biosimilars in the regulated markets, such as Europe, is not an easy task. Thus, Sandoz currently has three marketed biosimilars, Omnitrope®, Binocrit® and Zarzio®, accounting for nearly half the global biosimilars market.

Sandoz's biosimilar sales at $185 mn in CY10 were up 63% Y-o-Y and the company currently has an unmatched pipeline with 8-10 molecules in various development stages. **Sandoz** is also very much focused on monoclonal antibodies. Thus, Sandoz has created a strong biosimilars pipeline in view of the upcoming opportunity. Biologics, with estimated sales of about $51 bn, is likely to lose patent protection by 2015.

Hence, to our mind, Sandoz is the undisputed pioneer of biosimilars, having developed and launched both the first-ever biosimilar product in the US and EU (recombinant human growth hormone in 2006) markets, as well as the first complex glycosylated – biosimilar recombinant human erythropoetin alfa in 2007. With the EU approval and launch of biosimilar G-CSF (filgrastim) in 2009, currently Sandoz is the only company that has maximum biosimilars launched in the EU markets. Currently, the company has three products in the European market and two in the US. Sandoz's recombinant human growth hormone is also available in the US and Australia, and has been approved in Canada and Japan, under different regulatory pathways. Plus, Sandoz also has an unmatched biosimilar pipeline, with numerous projects in various stages of development, including monoclonal antibodies. The market opportunity for biosimilars is enormous and Sandoz, as the pioneer and global leader in biosimilars with a comprehensive pipeline, is best positioned to capitalize on the opportunity.

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Teva appears second best positioned company to benefit from the biosimilars opportunity

Teva forayed into the biosimilars space with the acquisition of Sicor in 2004, along with its biosimilars manufacturing facilities that produces granulocyte colony stimulating factor (G-CSF), G-interferon alpha 2B and HGH, which are sold in Eastern Europe, Africa and other developed countries.

Teva has one product in the European market (Tevagrastim) and further improved its biologics capabilities through the acquisitions of Barr Pharmaceuticals and CoGenesys, both US based companies in 2008. In 2009, Teva formed a strategic partnership with Swiss custom manufacturer, Lonza to jointly develop, manufacture and market biosimilars. Teva will be responsible for pre-clinical and clinical development, commercialization and intellectual property/legal activities, while Lonza will manage process development, scale-up and manufacturing of clinical and commercial material. The cost and profitability of the joint venture will be shared equally by both the companies. Plus, Teva now also has its biosimilars R&D facilities in Lithuania, Israel and China

Teva generated biosimilars sales of $112 mn in CY10, accounting for about 30% of the global biosimilars market. Biosimilars sales in CY10 were up a healthy 51% Y-o-Y, though the base was apparently quite low. Currently, biosimilars sales accounted for just 0.7% of Teva's overall sales.

Teva is now also developing a copy of Roche's Rituxan, the world's second-biggest-selling cancer drug and in May 2010, the company began recruiting patients with rheumatoid arthritis for a clinical trial comparing its biosimilar copy, TL011, with Rituxan, sold outside the US as MabThera, according to the US National Institutes of Health website. In September 2010, Teva expanded the tests to include patients with non-Hodgkin's lymphoma. Rituxan has patent protection in the US until 2018 and in the rest of the world through 2013. Apart from this, TEVA has a strong biosimilars pipeline and also plans the US approval of Neutroval (biosmilar of Neupogen) at the earliest.

Thus, in view of Teva's strong pipeline and manufacturing, R&D, marketing and legal capabilities, we believe that the company is likely to be among the best positioned players to benefit from the upcoming biosimilars opportunity.

Biocon, the best placed Indian company to tap the Insulin biosimilars market

Biocon was an early entrant in the biosimilars space by capitalizing on its experience and facilities in fermentation. Biocon has been focusing strongly on Insulin and Insulin analogs and has created a strong pipeline of anti-diabetic drugs, including human insulin, recombinant insulin, pen devices of the insulin, reusable and disposable forms of insulin, Glargine, Aspart and Lispro, and last but not the least, oral insulin.

Management does not provide the exact percentage of Biocon's biosimilars sales, though a majority comes from the domestic market. Indian Pharma players in the biosimilars space still earn most of their biosimilars revenue from the domestic market.

Apart from insulins, Biocon is now focusing on other biosimilars, such as EPO, G-CSF, Tarcolimus and MMF, as well as Mabs. Recently, Biocon also entered into a $350 mn partnership agreement with Pfizer for marketing four of its insulin products. The agreement includes the commercialization of Biocon's biosimilar versions of insulin and insulin analog products - recombinant human insulin (also called Insugen), Glargine, Aspart and Lispro. Pfizer will have exclusive rights to commercialize these products globally, with certain exceptions, including co-exclusive rights for all of the products with Biocon in Germany, India and Malaysia. Pfizer will also have co-exclusive rights with existing licensees of Biocon with respect to some of the products, primarily in a number of developing markets. Biocon will remain responsible for the clinical development, manufacture and supply of these biosimilar Insulin products, as well as the regulatory activities to secure approval for these products in various geographies. Biocon's recombinant human insulin formulations has been already approved in 27 countries in the developing markets and commercialized in 23, while Glargine was first launched in India in Q1 FY11. The company's filings in the other markets will take place subsequently. The potential market for these four products, according to management is likely to be worth about $20 bn by 2015, up from its current market of about $14 bn. Biocon hopes to combine the synergies of Pfizer's marketing and distribution networks and its own cost-effective developing and manufacturing capabilities to grab a pie of the $14 bn biosimilars insulin market, which are expected to replace the conventional insulins once they go off-patent in the major markets, such as the US and Europe. Moreover, the company has developed a disposable pen devise with Ypsomed and a reusable pen devise with an undisclosed major pen manufacturer, with the reusable pen devise likely to be launched in H2FY12.

Apart from PFE, Biocon has entered into partnerships with a Cuban partner for its BioMab (an indigenously developed molecule) and Mylan, and is searching for partner in other markets, such as Germany as well as the RoW markets. Biocon has also carried out the registration of insulin products in various emerging markets, like Brazil, Russia, Mexico, China and others.

Thus, Biocon plans to make a huge investment in the biosimilars space and is setting up a new facility in Malaysia at an initial investment of about $160 mn. The company plans to spend an additional $150 mn towards the facility in order to meet PFE's requirements and further increase its capacity. In view of the complexity related to Insulins, most players, including Sandoz and Teva, have not ventured into this biosimilars segment, which we believe, will provide Biocon with an advantage over the other players. As a result of this complexity and in spite patents on human insulins i.e. Novolon and Humulin, having already gone off-patent, there is no generic competition for these products and patent holders, such as Nova-Nordisk and Sanofi-Aventis, have been able to continue enjoy the market without any price erosion. Other small companies, like Poland based Bioton and Polfa Tarchomin, China based Tonghua Dongbao, Wanbang BioPharma, Gan & Lee, Kexing Biotech and Zhuhai United Labs and India based Wockhardt, have created a pipeline to tap the insulins opportunity, though Biocon seems the best positioned in this space.

Biocon is already carrying out Phase III trials on Insugen in Europe and plans to launch it in 2013-2014. Thus, among the other players tapping the market for insulin and its analogs, Biocon appears best positioned to capitalize on the opportunity, in view of its partnerships with various players and a strong pipeline.

Biocon is already carrying out Phase III trials on Insugen in Europe and plans to launch it in 2013-2014. Thus, among the other players tapping the market for insulin and its analogs, Biocon appears best positioned to capitalize on the opportunity, in view of its partnerships with various players and a strong pipeline

DRL likely to grab a sizable chunk of biogeneric honey pot

Unlike Biocon, which has focused on insulin and analogs, DRL has focused on first generation biosimilars other than insulin and analogs. Over the years, DRL has made investments to the tune of about Rs.2.5-3.0 bn for setting up a biosimilars facility along with fermenters. DRL currently has 3 biosimilars and plans to launch another 8 biosimilars in the next eight years.

One of DRL's products, Reditux (Rituximab) that is used in the treatment of non-Hodgkin's lymphoma, is among the company's top ten brands, with annual revenue of over Rs.240 mn. Biosimilars currently accounts for just 5% of the company's total sales, out of which about 70% comes from the domestic market and the remaining from the other emerging markets, like Peru, Chile and Brazil. DRL started out with the launch of generic G-CSF in 2001 and later launched Reditux in 2007 and Cresp (darbepoetin alfa) in FY10.

The company is also working on several other biosimilars, with one of them being in the late stage clinical trials. DRL is now focusing on Mabs, the next wave of biogenerics by 2014, and plans to launch its products in Europe. DRL launched Grafeel in 2006 in Brazil and is now in the process of filing for the launch of Filgrastim (Grafeel) in Europe. Betapharm, DRL's subsidiary in Europe, will act as its conduit to the biosimilars market.

In view of the uncertainties related to margins and returns in the biosimilars space, DRL has been quite cautious in its investments in this segment and is looking at entering into partnerships with emerging players for foraying into various emerging markets, like Russia, Turkey, etc. In terms of R&D set up, DRL has a strong scientific pool of over 400 scientists, with R&D centres located in Hyderabad and the US, for carrying out biosimilars research. Moreover, the company has a pipeline of seven biosimilars and will launch at least one product every year.

Thus, in view of their robust pipeline, as well as strong R&D, manufacturing, marketing and legal capabilities, we believe that DRL along with Biocon are the two most well positioned companies in the Indian market to benefit from the upcoming biosimilars opportunity.

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IMPORTANT DISCLOSURES

Price Target

Price targets (if any) are derived from a subjective and/or quantitative analysis of financial and non financial data of the concerned company using a combination of P/E, P/Sales, earnings growth, Discounted Cash Flow (DCF) and its stock price history

No ratings have been given in this report.

FIRST GLOBAL
Nirmal, 6th Floor, Nariman Point,
Mumbai - 400 021, India.
Dealing Desk (India):
Tel. No.: +91-22-400 12 400
Email: fgasiasales@bloomberg.net

FIRST GLOBAL (UK) Ltd.
13, Regent Street, London SW1Y 4LR,
United Kingdom
Dealing Desk (UK & Europe):
Tel. No.: +44-203-189 0057
Email: uk@fglobal.com