

**WHITE PAPER**

# GAINING MARKET SHARE IN THE GENERIC DRUG INDUSTRY THROUGH ACQUISITIONS AND PARTNERSHIPS

DAVID HARDING  
david.harding@thomsonreuters.com

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# INTRODUCTION

In 2010, we saw a number of deals in the pharmaceutical sector, although the size of the deals was considerably smaller than in 2009. In 2009, while merger and acquisition (M&A) activity in many sectors declined sharply, banks remained comfortable extending loans for deals in the healthcare industry. Regardless of economic climate or uncertainty surrounding the Congressional healthcare legislation at the time, they considered healthcare a growth sector. Thus, while the volume of deals across all sectors was down in 2009, deals in healthcare were up from 2008.<sup>1</sup>

Among the deals in 2009 were such high-profile transactions as Pfizer's acquisition of Wyeth (\$68 billion) and Merck & Co's acquisition of Schering-Plough (\$41 billion). In 2010, Abbott acquired Solvay for \$6.2 billion.

Generic companies looking to increase scale, revenue, market share, and competitive advantage have also been active with mergers and acquisitions. Recent examples include Teva's acquisition of ratiopharm and Mylan's acquisition of Bioniche.

In this white paper, Thomson Reuters draws upon unique intelligence from Newport Premium™ and the Newport Generic Deals Module to analyze deal making in the rapidly growing and changing global market for generic pharmaceuticals. We consider how generic companies have responded to challenges through vigorous M&A activity and partnerships, driven by need for:

- Backward integration into active pharmaceutical ingredients
- Rapid geographic expansion into smaller and emerging markets
- Aggressive portfolio build-outs in niche, specialty, and biologics products

<sup>1</sup> Gaining Market Share in The Generic Drug Industry Through Acquisitions and Partnerships

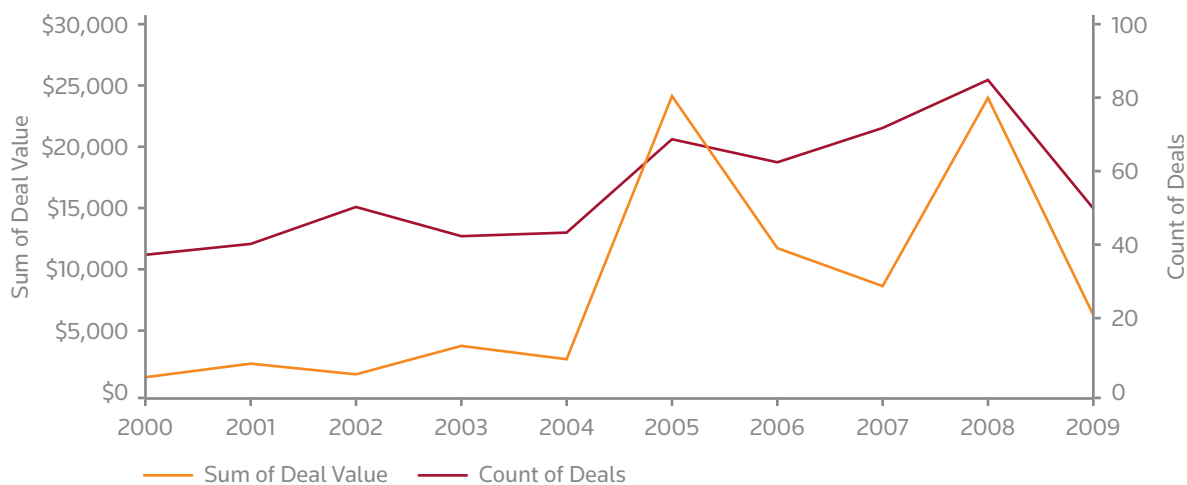
## KEY DRIVERS

Several factors have fueled rapid growth in the global generic pharmaceutical industry, including governments' and payers' need to rein in rapidly increasing healthcare expenditures, a growing middle class in emerging markets, and a longer life expectancy. A large number of patent expiries for innovator drugs, many of them blockbusters, has also contributed to the generic industry's growth. The global prescription generic industry, worth less than \$50 billion in 2004, now stands at over \$80 billion. If a more general definition of off-patent medicines is used to define generics, estimates have placed the size of the industry at closer to \$150 billion.<sup>2</sup> In the United States alone, generic sales have more than tripled since 2000 and now exceed \$51 billion.<sup>3</sup>

The rapid growth of the generic industry has come with a number of challenges, such as heavy competition, including from authorized generics in the United States. Government-mandated price cuts and the introduction of lowest-price tendering in certain European markets have also been concerns. All contribute to diminishing prices and ever decreasing margins. Generic companies have had to overcome these challenges by achieving economies of scale, diversifying their product portfolios, becoming vertically integrated across the manufacturing process, and expanding their geographic presence, especially into emerging markets. Many generic companies have relied on M&A rather than organic growth to weather the storm.

Figure 1 shows the amount spent on M&A activity in the generic industry between 2000 and 2009. Both the number and total amount spent on deals have grown over the years. In 2005, a year which saw an unusual amount of M&A activity, there was over \$24 billion in M&A within the generic industry, fueled by three deals totaling nearly \$16 billion (Sandoz's acquisitions of Hexal & Eon for \$8.2 billion and Teva's acquisition of Ivax for \$7.5 billion).

**FIGURE 1: Total Spend on M&A in the Generic Drug Industry Between 2000 and 2009**

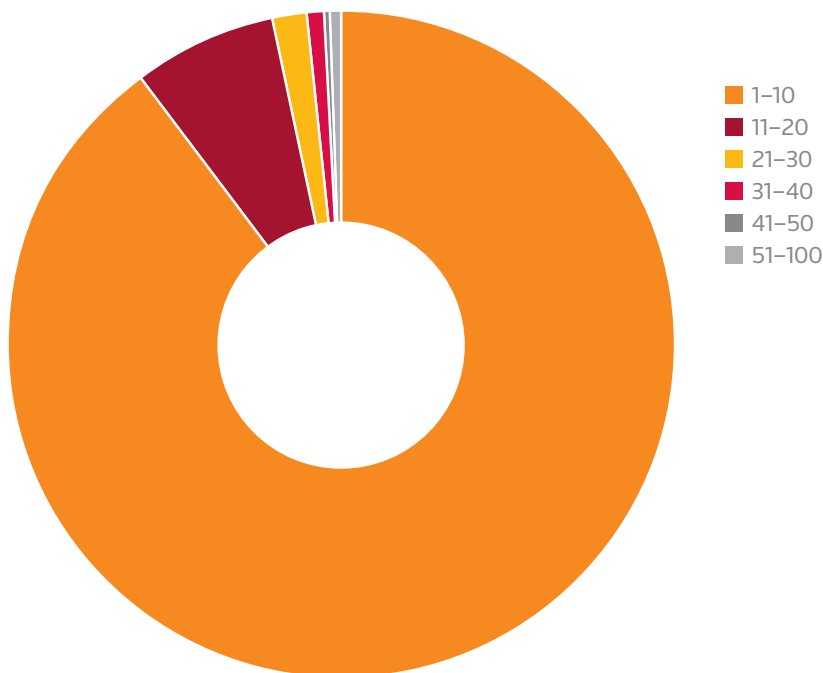


The four largest generic companies worldwide in terms of sales, Teva, Mylan, Sandoz, and Watson, which account for nearly 50 percent of generic prescriptions in the United States,<sup>4</sup> and nearly 40 percent worldwide,<sup>5</sup> have all used M&A to gain market share in the United States and globally.

Teva's strategy has been, and according to its leaders will continue to be, growth through M&A activity. Companies within the Teva group spent over \$25 billion on acquisitions between 2000 and 2009. Teva was able to increase its market share in the United States through the acquisition of Miami-based Ivax Pharmaceuticals in 2005, and gained further industry dominance when it acquired Barr Laboratories in 2008. The most recent acquisition by Teva was that of ratiopharm for \$5 billion. In a clear example of Teva's growth, a \$20,000 investment in the company in 1990 would have been worth \$1.6 million in 2009.<sup>6</sup>

Although M&A activity has not been confined exclusively to the top players in the generic industry, as Figure 2 shows, since 2000, most of the M&A dollars have gone into making the top 10 players even larger.

**FIGURE 2: M&A Spend Distribution by Tier Across Today's Top 100 Generic Companies Between 2000 and 2009**



### INTEGRATION OF API MANUFACTURING

Early access to high-quality active pharmaceutical ingredients (API) that are not infringing patents is critical to success in regulated finished-dose markets as a significant part of generics' profits is made during the early days of their availability. Pricing pressures and the need for supply chain control are also common challenges for generic pharmaceutical companies.

Mylan became backward integrated into API manufacturing through its August 2006 acquisition of a 71-percent stake in India-based Matrix Laboratories. The \$736 million deal gave Mylan global presence in formulations and secured access to an established global API manufacturer. Prior to the acquisition by Mylan, Matrix had acquired API manufacturing operations across India (Concord Biotech, Astrix Laboratories) and China (MChem Laboratories).

Watson purchased India's API manufacturer Sekhsaria Chemicals Ltd for an undisclosed amount in April 2006. Acquiring Sekhsaria, with 15 U.S. Drug Master Files (DMF) at the time of the acquisition, was a strategic move that gave Watson access to a low-cost manufacturing base for both API and intermediates from a growing company with its own aspirations to enter the U.S. market. Today, Watson also owns Changzhou Watson Pharmaceuticals Company in China and Resolution Chemicals in England, both of which have been inspected by the U.S. FDA.

Prior to being acquired by Teva, both Ivax and Barr had API manufacturing facilities of their own, mainly added through acquisitions. It was Barr's acquisition of Croatia's Pliva for \$2.5 billion in 2006 that gave Barr access to API manufacturing facilities for the first time. In fact, as a result of all acquisitions since 1980, Teva has acquired more than 250 DMFs and organizations connected to the manufacture of nearly 200 different molecules, a measure of the continued importance of access to API behind the scenes of M&A activity. In all, 39 of the industry's Top 50 generic companies are now backward integrated and have at least one or more subsidiaries that manufacture API. Germany's STADA remains the only Top 10 player with no API manufacturing capability.

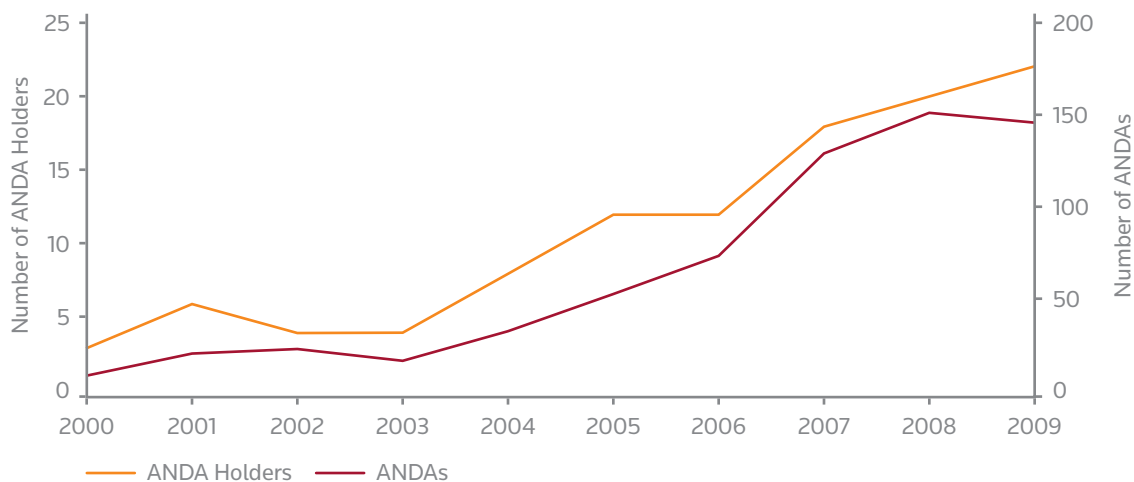
Numerous multinational companies that took advantage of India's low-cost manufacturing base are now also turning to China. For example, Actavis acquired a 90-percent stake in China-based Zhejiang Chiral Medicine Chemicals in March 2008 for \$7.24 million. This gave the company access to ergot alkaloids and other CNS drug ingredients such as gabapentin, for which Zhejiang Chiral has a U.S. DMF. Teva's acquisition of Zhejiang Wanma Pharmaceutical in 2006 and the three U.S. DMF filings that have occurred since at this site demonstrate Teva's willingness to consider a lower-cost API manufacturer in China as well.

## BUILDING ON API EXPERIENCE

Major India-based generic companies have increased their global market presence by taking advantage of their domestic low-cost manufacturing landscape as well as their years of experience manufacturing and supplying API to regulated markets. A number of these companies have also started supplying finished dose products to regulated markets, thus contributing to increased competition in generic markets.

In recent years, the number of ANDAs (abbreviated new drug applications) belonging to Indian companies has skyrocketed. Most of the Indian dose companies present in the U.S. market first gained experience there by supplying API. Of the 29 Indian companies with final or tentative ANDA approvals in the United States, only one, Claris Lifesciences, does not hold DMFs.

**FIGURE 3: Number of Indian ANDA Holders and Total ANDAs 2000 to 2009**



In all but three of the 28 cases where the Indian company holds both DMFs and ANDAs, the DMF filings precede ANDA approvals, often by more than a decade. Two of the exceptions are due to Indian companies acquiring existing ANDAs that used to belong to different companies (in the case of Glenmark and Intas). One of them is due to an Indian company acquiring a U.S. generic (Wockhardt acquired Morton Grove in 2007).

While some of the Indian companies have upgraded their existing facilities or built new FDA-approvable facilities from scratch, others have capitalized on acquisitions to gain immediate market share, among them Sun Pharmaceuticals. It acquired Caraco in 2004 for \$42M, and in 2010, gained a controlling interest in Israel's Taro, a company with a strong North American presence.

Another API manufacturer that has grown in finished dose markets through acquisitions is Dr. Reddy's Laboratories. In 1999, Dr. Reddy's acquired India's Cheminor Drugs and American Remedies for \$171 million and \$18.8 million respectively. While in 2002 the company had already begun expanding onto the international stage through the acquisition of BMS Laboratories Limited and Meridian Healthcare in the UK, its first major international acquisition came in 2006, when it acquired Betapharm Arzneimittel GmbH in Germany for \$571 million.

In all, Indian-headquartered generic companies and API manufacturers have spent over \$2.7 billion on M&A since 2000.

## EMERGING MARKET-FOCUSED DEALS

In 2010, the pharmaceutical industry in such established markets as the United States, Europe, and Japan was expected to grow at single-digit rates. Meanwhile, the pharmaceutical industry in emerging markets was expected to continue its double-digit growth rate. Therefore, it is not surprising that multinational generic companies and most major innovators alike were interested in expanding in emerging markets. While a few companies tried to go solo, many pursued M&A and partnership agreements as a means to enter these markets.

There has been considerable interest in the markets of Latin America. Within the same week in April 2009, Sanofi-Aventis acquired Laboratorios Kendrick, a leading Mexican generic company for \$35 million and Medley, Brazil's number one generic drug company, for \$689.6 million. In 2010, in Brazil alone, we have seen Pfizer acquire Laboratorio Teuto, Watson buy Brazil's Moksha<sup>8</sup>, and GSK gain Laboratorios Phoenix.

Teva gained presence in South America with the acquisition of Ivax, which had acquired Laboratorio Chile SA, the country's largest pharmaceutical firm,<sup>7</sup> for \$453.9 million in 2001; Laboratorios Fustery SA de CV and the Calzada del Hueso Manufacturing Complex in Mexico, in 2000 and 2004, respectively; and Laboratorios Elmor SA in Venezuela in 2000.

As a means of expanding into Central and Eastern Europe (CEE), Ranbaxy acquired Romania-based Terapia SA in 2006 for \$324 million. Prior to being acquired by Sanofi-Aventis, Zentiva actively used M&A to strengthen its position in CEE by acquiring Sicomed, Romania's leading generics company, for \$102 million in 2005<sup>8</sup> and Turkey's Eczacibasi for \$675 million in 2006.

Mid-tier Indian generic players have been highly active, expanding into other markets in the past years through a variety of partnerships, joint ventures, and acquisitions. For example, Strides Arcolabs ventured into Canada, Italy, South Africa, Singapore, and Australia; Jubilant into the United States, Canada, and Belgium; and Lupin into Australia, Philippines, Germany, and Japan.

### Case Study: Japan

Over 20 percent of Japan's population is age 65 or older, and by 2050 that number could become 40 percent. This is one of many factors contributing to Japan's burgeoning healthcare costs, which experts predict will reach 10 percent of GDP by 2020.<sup>9</sup> Historically, the Japanese public has considered generics inferior in quality, further increasing healthcare costs as even off-patent drugs have encountered little generic competition.

Among the measures taken to decrease healthcare costs, the Japanese MHLW (Ministry of Health, Labor, and Welfare) began a campaign in 2007 to increase awareness of generic drugs as a safe alternative to brand-name pharmaceuticals, and set a target of achieving a 30 percent market share for generic drugs (by volume) by 2012.<sup>10</sup> The Democratic Party of Japan (DPJ) Government has also signaled strong support for generic substitution and has set a target of 50 percent market share for generic drugs (by volume) by 2025.<sup>11</sup> Initiatives like these are having an impact on the year-over-year growth rate of generic market share in Japan. In 2002, the market share of generic drugs was 12.2 percent and by 2007 it had risen to 17.2 percent.<sup>12</sup> By September 2009, generics had gained over 20 percent market share in Japan.<sup>13</sup>

Numerous foreign generic companies, among them many from India, have tried to enter the Japanese market through both M&A and alliances. Ranbaxy was ahead of the curve, having acquired a 50-percent stake in Nihon Pharmaceutical Industry Co. Ltd in 2005 (the deal has since been terminated). Zydus Cadila took the M&A approach by acquiring Nippon Universal Pharmaceutical Co. Ltd for an undisclosed amount in April 2007, and Lupin Ltd followed with acquisition of a 90-percent stake in Kyowa Pharmaceutical Industry Co. Ltd in October 2007 for \$85.3 million.

Teva, having struggled for years to make headway under its own steam in this important and largely untapped generic market, was able to expand its presence quickly in Japan through the establishment of a 50:50 joint venture with Kowa in 2008. Sanofi's generics arm has followed much the same route, tying up with Japanese generic maker Nichi-Iko.

## NICHE PRODUCTS AND BIOLOGICS

Having a diversified product portfolio allows a generic company to capitalize on more opportunities. Since many major generic pharmaceutical companies started with limited dose capabilities, (e.g. oral solids where barriers of entry are minimal) the need to diversify product offerings has become a driver for acquisitions.

For example, Barr's acquisition of Pliva gave the company access to new drug delivery technologies and biotechnology capabilities; prior to the acquisition, Barr was focused primarily on oral solids. Meanwhile, Watson's acquisition of Andrx gave it access to controlled release technology. A number of acquisitions since 2000 have focused on gaining or expanding access to injectables, among them Sandoz's acquisition of Ebewe and Sabex Holdings, Fresenius Kabi's acquisition of Dabur, and more recently Mylan's acquisition of Bioniche.

Perhaps the ultimate niche products are follow-on biologics. Besides the estimated \$100 to \$200 million in development costs, which stand in stark contrast to the \$1 to \$5 million in development costs for a typical small-molecule generic drug, there are also the costs of building a suitable manufacturing facility, estimated to be \$250 million to \$1 billion. Due to the high development, manufacturing, and market costs, competition is more likely to resemble brand-to-brand rather than brand-to-generic competition, so discounts will not be as great as those offered for small molecule generic substitutions.<sup>14</sup> Because of these barriers to entry, it is expected that competition will be limited strictly to larger companies with sufficient resources and capabilities, either in-house or through partnerships. Thomson Reuters expects access to generic biologics to fuel M&A and other deal-making activity among both innovators and generic drug companies for the foreseeable future. (To learn more about biosimilars, please subscribe to the Biosimilars White Paper by Thomson Reuters at: [http://interest.science.thomsonreuters.com/info/newport\\_whitepapers](http://interest.science.thomsonreuters.com/info/newport_whitepapers))

Sandoz, Novartis's generics division, is one company with the capabilities and financial resources to be a major player in the global follow-on biologics market. It already has several biosimilars in the European market. Sandoz signed a deal with Momenta Pharmaceuticals in 2006, gaining a 13-percent share in the company and access to Momenta's novel technology of sequencing sugar molecules.<sup>15</sup> Sandoz also acquired Ebewe Pharma GmbH in September 2009, presumably to combine the biopharmaceutical experience of Sandoz with the expertise Ebewe Pharma has with injectable cancer medications.

Teva, another company already selling follow-on biologics in Europe, formed a joint venture with Swiss-based Lonza AG for the development, manufacture, and marketing of follow-on biologics in January 2009. Because Lonza has long been in the biologics business and has manufacturing agreements with numerous innovator companies such as ImClone and Novartis, this joint venture is a well-positioned move for both companies to grow in the biosimilars marketplace. Teva's biosimilar platform is also likely to be aided by the acquisitions of Sicor in 2004, Tianjin Hualida in 2006 and Cogenesys in 2008.

Hospira's acquisition of Bresagen in 2006 for \$16 million gave it access to protein manufacturing and cell line development. In September 2009, Hospira acquired the rights for filgrastim biosimilar from Pliva in addition to entering into an arrangement with South Korea's Celltrion for the development of a number of biosimilars.

In September 2010, Mylan acquired Bioniche, a manufacturer of injectable products. This move will also help Mylan execute its biologics strategy and build on its biosimilars partnership with Indian company Biocon. Top 10 player Actavis is also gearing up for biosimilars by acquiring a controlling share interest in BioPartners Holdings AG, currently held by Poland's Bioton.

Big pharmaceutical companies anticipate future growth opportunities in the biosimilars market as well. In March 2009, Merck acquired Insmid Inc's follow-on biologics platform for \$130 million, and in October 2010, Pfizer announced a global agreement with Indian company Biocon for the development of biosimilars, mainly in the field of diabetes.

## INNOVATOR INTEREST IN GENERICS

As innovators have witnessed the growth in the generic industry and struggle to cope with pending patent expiries, many of them have turned to acquisitions and supply agreements to expand into generic drug markets as well.

Novartis is one of the few innovator-focused pharmaceutical companies that stayed active in the generic drug industry even while other pharma companies divested their generic arms in the 1990s. Novartis not only used M&A as a means to become involved with generics, but also as a means to gain entry into new generic markets. After re-branding their numerous generics businesses as Sandoz in 2003, Novartis (Sandoz) went on to become one of the largest generic pharmaceutical companies worldwide, mainly through acquisitions.

After divesting numerous generic-focused facilities to companies such as Teva (Israel), Torrent (India), and Actavis (Iceland), Pfizer has ventured back into generics, having created a business unit in 2008 appropriately named “Established Products,” for the purpose of marketing generic drugs. Pfizer signed an agreement with Aurobindo Pharmaceuticals (India) in March 2009 for multiple generic oral solid and injectable drugs and extended the agreement in June 2009. In January 2010, Pfizer entered into a collaboration agreement with Strides Arcolab of India, for the supply of 40 off-patent products, including mostly injectable anti-cancer treatments. A few months later, the two companies expanded their partnership to include niche sterile injectable products.

Pfizer indicated in 2009 that it would seek acquisitions in the generic industry,<sup>16</sup> and made an offer for Germany’s ratiopharm as well as showed interest in Iceland’s Actavis. Pfizer was also interested in Ranbaxy Pharmaceuticals, the company that was the first to file an ANDA Paragraph IV patent challenge for Pfizer’s mega-blockbuster drug Lipitor® (atorvastatin) in January 2003.

Ultimately, Ranbaxy was acquired by Daiichi Sankyo, a Japanese innovator drug company, in a deal valued at \$4.6 billion. Daiichi Sankyo’s reasons for the acquisition included not only ownership of the eventual revenue driver of generic atorvastatin in the United States, but also gaining Ranbaxy’s access to the rapidly-growing Indian pharmaceutical market as well as its low-cost manufacturing and research capabilities.

Both Gilead Life Sciences and GlaxoSmithKline have signed agreements with South Africa’s Aspen Pharmacare for distribution of drugs in that region; however it was GlaxoSmithKline that in May 2009 acquired a 16-percent stake in Aspen Pharmacare. It was rumored that GlaxoSmithKline was also interested in the Ranbaxy acquisition in 2008<sup>17</sup> and in another Indian generic drug manufacturer, Piramal Healthcare, in 2009.<sup>18</sup> Furthermore, GlaxoSmithKline signed a development and commercialization license with Dr. Reddy’s in June 2009, and in September 2009 was rumored to have interest in acquiring them as well. In 2010, GlaxoSmithKline expanded its business in Latin America by acquiring Laboratorios Phoenix in Argentina. Phoenix has a broad portfolio of branded generics covering therapeutic areas including cardiovascular, gastroenterology, metabolic, and urology. The deal also includes a manufacturing facility near Buenos Aires.

In a stated effort to strengthen and diversify its business model for generics in emerging markets,<sup>19</sup> Sanofi-Aventis, an innovator pharmaceutical company, has perhaps been the most aggressive in its M&A activity in the generics drug industry in the recent past. In 2008, in a deal worth \$2.6 billion, it acquired Zentiva, a Czech Republic-based generic drug company, allowing Sanofi-Aventis access to numerous markets in Central and Eastern Europe. In April 2009, Sanofi-Aventis acquired Laboratorios Kendrick, a leading Mexican generic company for \$35 million and Medley, Brazil’s number one generic drug company, for \$689.6 million. In July 2009, Sanofi-Aventis inked two more deals that strengthened its position in the generic drug industry with the acquisitions of Indian vaccine manufacturer, Shantha Biotechnics, and the Swiss generic drug manufacturer, Helvepharm. Sanofi-Aventis is also among the companies that showed interest in Germany’s ratiopharm<sup>20</sup> as well as Iceland’s Actavis.<sup>21</sup>

One of the most active deal makers in 2010 was Abbott. After obtaining a diverse portfolio of branded generics products and a significant presence in emerging markets by acquiring Solvay Pharmaceuticals at the beginning of the year, Abbott agreed to pay \$3.72 billion for Piramal Healthcare's Indian formulations business in May and announced collaboration with Zydus Cadila (India). According to Abbott, the deal will give them the Number 1 position in the Indian pharmaceutical market. The collaboration agreement between Abbott and Zydus Cadila covers the development and commercialization of branded generics in 15 emerging markets. Initially, Abbott will commercialize 24 products from the Zydus portfolio with an option to commercialize more than 40 others. The products cover a number of therapeutic areas, including pain, cancer, respiratory, neurological, and cardiovascular diseases.

## CONCLUSION

The past decade brought significant consolidation in the generic industry. Given the tremendous pressure on both innovator and generic companies to maintain growth, this trend is likely to continue. Generic companies are looking to increase scale and gain access to high-quality API while pursuing geographic diversification, access to rapidly-growing emerging markets, product mix diversification, and access to products with barriers to entry (e.g. biosimilars). Thomson Reuters expects that innovator companies' interest in the generic market will continue as well as they try to fill revenue and profit gaps due to pipeline depletion and upcoming patent expiration on many major products.

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