

Case 21

Teva Pharmaceutical Industries, Ltd

Tarun Khanna
Krishna Palepu
Claudine Madras

In Israel we have a 1970s song based on a poem from 1953 by Amir Gilboa about Theodor Herzl.¹ It has a line in it about Herzl: "Suddenly a man rises in the morning, feels he is a people, and starts walking." That is exactly what Hurvitz did. Suddenly he woke up in the morning, feels he is a giant world class company, and starts walking. No one, aside from Herzl, has accomplished anything as remotely as impressive in this country as Hurvitz. It was impossible, a million to one odds at best, and he still did it. He woke up one morning and started walking.

—Ori Hershkovitz, equity analyst at Tel Aviv-based Leader & Company

- 1 The markets had not been kind to Teva Pharmaceutical during the first half of 2006. The stock had plunged nearly 30% from January 1 to June 30, erasing billions of dollars from the company's market capitalization. Even good news, such as reports in July of Teva's wildly successful introduction of generic Zocor—the largest blockbuster drug ever to go off-patent—had failed to boost the stock significantly. Since nearly every retirement fund and mutual fund in Israel invested in Teva, this drop had been felt throughout the population, in effect amounting to every Israeli family losing NIS 3000, or \$675.¹
- 2 Teva was more than the world's leading producer of generic pharmaceuticals (see **Exhibit 1** for financials). It represented the gold standard of business in Israel. As the country's largest public company and first true multinational, it had avoided the traditional conglomerate model of early Israeli enterprises, choosing instead a highly focused approach embraced by later generations of successful Israeli firms. With revenues growing from \$91 million in 1985 to an estimated \$8.5 billion in 2006, the company had bred a new class of professional managers and scientists in the country. It had served as a bridge from Israeli science to the market and had been an important source of talent and capital for the growing biotechnology sector. It had also helped to catalyze the country's domestic capital markets by being one of the early companies to list on the Tel Aviv Stock Exchange in 1968.²
- 3 In 2005, Teva's \$7.4 billion acquisition of Ivax catapulted the company to the top position among global generics in what one reporter dubbed "Generics' answer to Big Pharma."³ Less than one year later, Teva filled 20% more prescriptions than Pfizer, the world's largest pharmaceutical company. It had a portfolio and pipeline twice the size of its next closest



Source: Professors Tarun Khanna and Krishna Palepu and Doctoral Student Claudine Madras prepared this case. HBS cases are developed solely as the basis for class discussion. Cases are not intended to serve as endorsements, sources of primary data, or illustrations of effective or ineffective management.

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¹ The most important early advocate for the establishment of Israel.

EXHIBIT 1A Teva Pharmaceutical Industries Income Statement (USD)

	2001	2002	2003	2004	2005
Revenue	2,077.4	2,518.6	3,276.4	4,799.0	5,250.0
Other Revenue	—	—	—	—	—
Total Revenue	2,077.4	2,518.6	3,276.4	4,799.0	5,250.0
Cost Of Goods Sold	1,230.1	1,423.2	1,757.5	2,546.0	2,770.0
Gross Profit	847.3	1,095.4	1,518.9	2,253.0	2,480.0
Selling General & Admin Exp.	358.7	406.4	520.6	696.0	799.0
R & D Exp.	107.2	165.0	213.5	338.0	369.0
Depreciation & Amort.	—	—	—	—	—
Other Operating Expense/(Income)	—	—	—	—	—
Other Operating Exp., Total	465.3	571.4	734.1	1,034.0	1,168.0
Operating Income	382.0	524.0	784.8	1,219.0	1,312.0
Interest Expense	(46.9)	(54.5)	(45.2)	(42.0)	(34.0)
Interest and Invest. Income	20.7	17.8	24.4	27.0	45.0
Net Interest Exp.	(26.2)	(36.7)	(20.8)	(15.0)	11.0
Income/(Loss) from Affiliates	0.8	(2.7)	1.5	(1.0)	2.0
Currency Exchange Gains (Loss)	(5.4)	(22.8)	11.8	(14.0)	10.0
Other Non-Operating Inc. (Exp.)	4.0	35.4	4.0	55.0	(25.0)
EBT Excl. Unusual Items	355.2	497.2	781.3	1,244.0	1,310.0
Restructuring Charges	(15.7)	—	(7.4)	—	—
Merger & Related Restruct. Charges	—	—	—	(14.0)	—
Impairment of Goodwill	—	—	—	—	—
Gain (Loss) On Sale Of Invest.	1.6	(0.5)	—	—	—
In Process R & D Exp.	—	—	—	(597.0)	—
Legal Settlements	—	—	100.0	(30.0)	—
Other Unusual Items	—	—	—	—	—
EBT Incl. Unusual Items	341.1	496.7	873.9	603.0	1,310.0
Income Tax Expense	63.6	84.8	181.5	267.0	236.0
Minority Int. in Earnings	0.7	(1.6)	(1.4)	(4.0)	(2.0)
Earnings from Cont. Ops.	278.2	410.3	691.0	332.0	1,072.0
Earnings of Discontinued Ops.	—	—	—	—	—
Extraord. Item & Account.	—	—	—	—	—
Change	—	—	—	—	—
Net Income	278.2	410.3	691.0	332.0	1,072.0

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EXHIBIT 1B Teva Pharmaceutical Industries Balance Sheet (USD)

	2001	2002	2003	2004	2005
ASSETS					
Cash And Equivalents	768.9	809.9	1,057.3	784.1	1,276.0
Short-Term Investments	21.2	235.7	322.1	256.8	935.0
Total Cash & ST Investments	790.1	1,045.6	1,379.4	1,040.9	2,211.0
Accounts Receivable	651.2	855.8	1,031.8	1,475.9	1,769.0
Other Receivables	166.4	218.9	300.6	398.4	—
Total Receivables	817.6	1,074.7	1,332.4	1,874.3	1,769.0
Inventory	570.2	781.1	1,004.6	1,286.3	1,114.0
Prepaid Exp.	—	—	—	—	316.0
Deferred Tax Assets, Curr.	—	—	—	—	95.0
Other Current Assets	—	—	—	—	—
Total Current Assets	2,177.9	2,901.4	3,716.4	4,201.5	5,505.0
Gross Property, Plant & Equipment	1,022.3	1,166.3	1,365.9	1,950.9	2,149.0
Accumulated Depreciation	(480.2)	(532.9)	(608.9)	(764.5)	(877.0)
Net Property, Plant & Equipment	542.1	633.4	757.0	1,186.4	1,272.0
Long-term Investments	141.9	277.3	396.7	806.5	278.0
Goodwill	466.1	560.3	647.5	2,572.4	2,462.0
Other Intangibles	103.0	158.4	269.1	695.2	635.0
Deferred Tax Assets, LT	—	—	—	—	76.0
Deferred Charges, LT	17.1	17.8	10.4	21.5	—
Other Long-Term Assets	12.1	78.2	118.8	148.5	159.0
Total Assets	3,460.2	4,626.8	5,915.9	9,632.0	10,387.0
LIABILITIES					
Accounts Payable	319.4	404.3	533.1	741.1	360.0
Accrued Exp.	50.6	63.7	86.5	120.9	587.0
Short-term Borrowings	202.8	176.1	291.7	390.0	764.0
Curr. Port. of LT Debt	3.7	566.5	352.5	170.4	111.0
Curr. Income Taxes Payable	24.4	141.0	179.8	190.6	205.0
Other Current Liabilities	137.2	172.6	251.3	590.9	733.0
Total Current Liabilities	738.1	1,524.2	1,694.9	2,203.9	2,260.0
Long-Term Debt	1,246.9	1,161.4	815.4	1,728.4	1,773.0
Minority Interest	2.2	4.9	6.7	10.9	8.0
Pension & Other Post-Retire. Benefits	10.4	13.8	13.7	16.9	11.0
Def. Tax Liability, Non-Curr.	39.0	43.7	34.6	212.3	219.0
Other Non-Current Liabilities	42.9	49.4	61.2	70.7	74.0
Total Liabilities	2,079.5	2,797.4	2,626.5	4,243.1	4,345.0

EXHIBIT 18 (Continued)

	2001	2002	2003	2004	2005
Common Stock	31.0	33.9	34.3	42.1	43.0
Additional Paid In Capital	480.6	481.5	1,159.3	3,035.0	3,369.0
Retained Earnings	970.4	1,345.7	1,960.3	2,171.4	3,081.0
Treasury Stock	—	—	—	—	(596.0)
Comprehensive Inc. and Other	(101.3)	(31.7)	135.5	140.4	145.0
Total Common Equity	1,380.7	1,829.4	3,289.4	5,388.9	6,042.0
Total Equity	1,380.7	1,829.4	3,289.4	5,388.9	6,042.0
Total Liabilities And Equity	3,460.2	4,626.8	5,915.9	9,632.0	10,387.0

Source: Capital IQ, <https://www.capitaliq.com/main.aspx>, accessed February 18, 2010.

competitor.⁴ With a 20% share of the U.S. generics market by revenue and number of prescriptions, it was by far the largest player in the world's largest market. Also, with the Ivax acquisition, Teva had gained the broadest geographic reach in the industry. One of the top players in Western Europe, it also had a significant operations in the fast-growing markets of Eastern Europe and Latin America, and had a presence in over 50 countries globally.

- 4 While Teva may have been Generics' answer to Big Pharma, Big Pharma was finally answering back. Novartis, one of the world's largest pharmaceutical companies and the only one with a consistently strong presence in generics over the last two decades, had spent \$10 billion on generics acquisitions since 2001. Novartis's generics unit, Sandoz, was now the second-largest generics company in the world. Other innovative pharmaceutical firms were aggressively fighting patent challenges through the legal process, through alliances with generics companies, and by moving to revive their own generics arms.

- 5 Low-cost firms from India, Eastern Europe, and elsewhere were also upping their game, emulating strategies that Teva itself pioneered over the last decade. Partly as a consequence, the pricing of generics in the U.S. market—the core of Teva's business for 20 years—had declined between 15% and 30% over the past three years.⁵ However, the U.S. and worldwide markets continued to grow as aging populations and rising healthcare costs created pressure for lower-cost alternatives to expensive drugs.

- 6 In these industry conditions, could the company maintain its annual growth rate of 33% of the last five years, and, if so, how? Teva could keep its focus on the U.S. generics market, with major blockbusters set to lose their patent protection over the medium term, and take advantage of the glut of small firms to grow its share during the inevitable consolidation. Alternatively, the company could focus on the global generics market, either on the large potential markets that were slowly opening up to generics, such as Germany, France and Japan, or on the newer markets, such as Latin America or Asia. Teva could also continue to move up the value chain from low-cost generics into more specialized generics such as drugs with complex delivery systems or "biosimilar" versions of large-molecule drugs. Most aggressively, Teva could finally become serious about expanding into specialized innovative drugs, becoming one of the few pharmaceutical companies to perform both functions in-house. While this strategy carried the company further from its core business, Teva had a long history of strong ties to local research talent, and had already successfully launched one blockbuster drug.⁶

⁶ A "blockbuster drug" is defined to have annual sales of \$1 billion or more.

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- 7 In the meantime, Teva also needed to guard against the innovative firms and low-cost players to make sure that, as the incumbent, it did not allow creeping complacency to become fatal. The industry had changed significantly over the past five years; and the market leader needed to change with it.

THE GENERIC PHARMACEUTICALS INDUSTRY

Innovative Pharmaceuticals⁶

- 8 In 2006, the worldwide pharmaceutical industry totaled approximately \$600 billion.⁷ Globally, the six hundred publicly traded pharmaceutical and biotechnology companies had a combined market capitalization of over \$1.5 trillion.⁸ The industry had grown at approximately 12% over the last five years, with typical returns on equity of 20%, among the highest of any industry. Industry profitability depended on vigorous patent protection, particularly in the largest markets. Within the United States, the Patent and Trademark Office granted official protection for 17 to 20 years to new chemical entities. However, because the patent clock began prior to FDA approval, this protection translated into 10–12 years of effective patent life, as measured from the introduction of the drug into the market to expiration. During this period, gross margins on patented drugs typically ranged from 85% to 95%.⁹
- 9 Pharmaceutical firms were valued based on their pipeline of new drugs in pre-approval stages, as well as the projected lifespan of drugs currently on the market. In 2005 and 2006, drugs totaling \$17 billion and \$21.3 billion of annual sales had lost patent protection. Some industry participants were pessimistic about the future of the traditional (non-biotech) pharmaceuticals firms. They cited that more than 70 drugs were set to lose patent protection by 2010, including 19 blockbuster drugs, with few products in the pipeline to replace them.¹⁰ As a consequence, annual industry growth was predicted to slow to 5% to 8% annually.
- 10 Pharmaceutical research was inherently a high-risk activity. One out of every 5,000–10,000 compounds tested became an approved drug,¹¹ and half of drug development costs were expended on drugs which never reached the market. Seven in every 10 marketed drugs did not produce revenues exceeding their R&D costs.¹² Drug development was a lengthy process, involving compound discovery, preclinical trials, three phases of clinical trials, and government approval. By the 2000s, the typical drug development duration from screening to approval was 10–15 years and cost \$800 million, versus \$140 million and \$320 million in the 1970s and 1980s (in real terms). Research and development costs typically accounted for 14% of these firms' revenues, or between \$30 and \$50 billion per year for large companies.¹³
- 11 Once the drug was approved, it was marketed using the pharmaceutical firms' considerable sales forces. Sales and marketing costs varied by therapeutic category and potential market size of the drug, but on aggregate ranged from 30–35% of firm revenues. These costs included both "drug detailing," in which trained representatives visited hospitals and targeted prescribing physicians, and direct-to-consumer advertising, which had been liberalized in the United States in 1997.

Generic Pharmaceuticals

- 12 Generic pharmaceuticals refer to "bioequivalent" versions of their innovative counterparts. Most often in tablet and capsule form but also available in syringes, inhalers, and other delivery devices, generics in effect duplicated the active compounds developed by the original drug maker. These drugs were subject to the same regulatory standards and could

EXHIBIT 2 Innovative and Generics Cost Structure Comparison (2005)

	Teva	Barr	Sandoz	Mylan	Pfizer	Merck	Novartis*	Sanofi-Aventis
Net sales (\$ ¹⁰)	5.3	1.1	4.7	1.3	51.3	23.8	32.2	35.5
Net sales	100%	100%	100%	100%	100%	100%	100%	100%
Gross profit	47%	70%	51%	56%	83%	78%	72%	74%
R&D expenses	7%	12%	9%	7%	14%	14%	15%	14%
SG&A	15%	29%	26%	14%	33%	36%	36%	29%
Op income	25%	32%	13%	25%	22%	31%	19%	10%
Return on equity	19%	22%	Na	10%	12%	26%	19%	5%

Source: Bank of America Securities, Company 20F and 10K filings.

*Including Sandoz

Market value of equity, priced mid 2006

only be manufactured and sold if the original drugs were not protected by patents. From a medical perspective, these drugs were largely identical to the versions of innovative firms and other generics producers.

- 13 Generics were typically priced significantly lower than their original versions because the drug makers did not need to recoup the massive costs of the initial research and development associated with drug discovery nor support the massive sales and marketing costs associated with introducing a new drug. See **Exhibit 2** for a comparison of the cost structures between innovative firms and generics firms. While the innovative and generics industries had both grown worldwide at around 9% to 10% annually since 2000 (see **Exhibit 3**), generics growth was expected to speed up to as much as 16% in major markets. Daniel Vasella, the CEO of Novartis, predicted that sales of generics would double to \$100 billion worldwide by 2010 from the \$52 billion in 2005.¹³

Generic Markets

- 14 **United States** The United States, by far the world's largest generics market, was the first major country to embrace unbranded generics with the enactment of the Hatch-Waxman Act in 1984. As a result of the act, generics penetration in the U.S. increased from 13% of the total number of prescriptions in 1983 to more than 50% in 2006 with prices close to 11% of the innovative products on a per-dose basis.¹⁴
- 15 The act contained two important provisions. First, it introduced the Abbreviated New Drug Application (ANDA) process which allowed generic drugs to shortcut the lengthy drug approval processes required by the Food and Drug Administration. Second, through its "Paragraph IV" provision, it allowed generics companies to challenge innovative drugs long before patent expiration. Crucially, it established a 180-day exclusivity period for the first company to submit an ANDA under a Paragraph IV challenge, providing incentives for generics competition. This exclusivity period set up a highly coveted duopoly for the first six months after the introduction of a generic drug. Paragraph IV had resulted in a vicious escalation in the legal battles between innovative companies and their generics counterparts, particularly with blockbuster drugs commanding multi-billion dollar markets.
- 16 During the exclusivity period, during which a generic drug faced competition only from its patented counterpart, the generic could be expected to capture up to 75% of the market by volume of prescriptions with discounts of 20% to 40% off the original drug price.¹⁵ Gross margins during this period were typically near 70% to 90%, close to the innovator's margins

EXHIBIT 3 Pharmaceuticals Industry Revenue and Growth

Pharmaceuticals Industry Revenues							Region Share of Pharma Market (2003)	
Revenues (\$bn)	2000	2001	2002	2003	2004	2005	CGR (%)	
Worldwide	362	395.1	431.3	470.8	513.9	561	9.2	North America
North America	152	171.1	192.7	216.9	244.2	274.9	12.6	Europe
Europe	79.6	85.3	91.3	97.8	104.8	112.2	7.1	Japan
Eastern and Central Europe	7.2	7.9	8.6	9.4	10.3	11.2	9.2	Africa, Asia, Australia
Japan	57.9	59.7	61.5	63.4	65.3	67.3	3.1	Latin America
East Asia and China	18.1	20.5	23.2	26.3	29.8	33.7	13.2	
India	3.6	3.9	4.3	4.7	5.1	5.6	9.2	
Latin America	25.3	27.6	30.1	33	36	39.3	9.2	
Rest of World	18.3	19.1	19.6	19.3	18.4	16.8	-1.7	
Generics Industry								
Revenues (\$, mm)	1998	1999	2000	2001	2002	2003	Past CGR (%)	Estimated Future CAGR ^a
Worldwide	27,180	29,750	32,600	35,900	39,400	43,300	9.8	10.0
United States	11,150	12,300	13,550	15,000	16,500	18,200	10.3	12.6
Western Europe	6,250	7,100	8,100	9,300	10,600	12,100	14.1	10.5
Japan	4,860	5,100	5,350	5,600	5,900	6,200	5.0	4.8
Rest of World	4,920	5,250	5,600	6,000	6,400	6,800	6.7	9.5

Source: Medical and Healthcare Marketplace Guide, 2001.

^aNovartis estimates.^bLaunched between 1997 and 2001.

of 90% to 95%. After the 180-day period expired and other generics competition entered the market, the pricing of the 180-day generic drug decreased significantly, although the company often maintained a higher market share than the new generic entrants. In a typical scenario, the pricing would decline to 90% off the innovative price, while the market share of the 180-day holder would decrease from 70% to 75%, to 30% to 40%, with the corresponding sharp decline in margins. These numbers differed across producers and with the number of competitors entering the market.

- 17 **Europe** The market for generics in the rest of the world varied greatly across countries. The European Union was slowly moving towards internal harmonization, although it was still far from achieving that aim. The United Kingdom and the Netherlands, the most competitive markets in the region, resembled the U.S. in their market structures. Pharmacists were free to substitute generic drugs for innovative versions at their discretion unless explicitly overruled by the physician, and prices were largely market driven. As a result, generic penetration was also high—49% of total prescriptions in the two countries in 2004—as governments, the public, physicians, and pharmacists generally accepted generics substitution.¹⁷ The United Kingdom had a \$2.9 billion generics markets that was expected to grow to \$5.6 billion by 2008.¹⁸

- 18 Germany and France, like most other countries in the region, were “physician-driven” or “branded generics” markets in which pharmacists could not substitute generics at their discretion. Generics companies operating in these markets branded and marketed their drugs directly to physicians in the same manner as innovative companies and, as a result, incurred the costs of supporting much larger sales forces and marketing activities than in pharmacist-driven markets. Prices for both innovative and generic drugs tended to be government regulated in these markets; therefore, discounts associated with generic drugs generally were much lower than in liberalized markets. While these markets had lower penetration rates than pharmacist-driven markets—12% in France and 41% in Germany by volume in 2004¹⁹—they were still some of the largest markets globally both in size and potential. Germany had a \$5.5 billion generics market in 2004 that was expected to increase to \$9.7 billion by 2008. The \$1.2 billion generics market in France was projected to grow even faster during the same period to reach \$3.3 billion by 2008.²⁰

- 19 **Rest of world** Japan, the world’s third-largest pharmaceuticals market, was also heavily regulated and had a generics penetration of approximately 10%.²¹ Japan and other East Asian markets had various structural barriers to generics substitution, including a perception by patients and many physicians that generics were of inferior quality. Physicians also both prescribed and dispensed drugs, generating a portion of their income from pharmaceuticals. Given this dual role, they had little incentive to substitute the lower-priced generics. Over time, however, penetration in Japan, like all the large markets, was expected to increase as its population aged and health care costs rose.

- 20 Developing markets, such as Latin America, Eastern Europe, Russia, India, and China were becoming increasingly attractive markets for generics as governments moved to provide higher-quality care and middle classes emerged—though with budget constraints that led to a strong preference for less costly generic drugs. For example, in Poland, Lithuania, and Hungary, generics penetration by volume in 2004 was 87%, 73%, and 50%, respectively.²² Many of these markets were physician driven, requiring all the corresponding sales and marketing activities, and were heavily government regulated.

Industry Players

- 21 Starting in the mid-1990s, the highly fragmented generics industry began to consolidate slowly and then a decade later, it experienced two competitive seismic shifts: the entrance of new types of competitors and the introduction of aggressive tactics by the innovative firms.

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Low-cost players began to emerge from newly competitive markets such as India (Ranbaxy, Dr. Reddy's Laboratories, Orchid, among others), Eastern Europe (Pliva, Aegis, and Gedeon Richter), and Iceland (Actavis). Indian firm Ranbaxy was one leader of this generation. The Indian market had long been heavily protected and the government had de facto allowed local firms to circumvent international patent laws to manufacture drugs domestically, a practice which ended in 2005 with India's commitments as a full member of the World Trade Organization. With fierce domestic competition and very low consumer ability to pay, India had among the lowest pharmaceutical prices in the world. For example, the country had over 100 brands of generic ciprofloxacin priced at an average of 63 cents for 10 tablets of 500 mg each, compared to \$51 for generic ciprofloxacin in the U.S.²¹ (However, a large component of the price differences between generics in the Indian and U.S. markets could be attributed to additional costs which would have to be borne by all participants, such as obtaining federal approval and maintaining quality standards, as well as the pharmacy markup.) Ranbaxy had used its advantages to compete abroad; by 2005, the company generated 80% of its \$1.2 billion revenues outside India. In mid-2006, Ranbaxy had the second-largest generics pipeline in the U.S. after Teva²² and set itself the goal of surpassing Teva globally by 2012.²³ However, it was still significantly smaller on an absolute scale, and revenue was increasing at a rate of 19% over the previous five years compared to Teva's 33%. See **Exhibit 4** for competitor information.

- 22 Generic pharmaceutical companies also faced new competition from innovative firms. In 2005 Novartis acquired two generics companies, Hexal (Germany) and Lion (U.S.), and merged them into its generics arm, Sandoz, placing it temporarily into the top position in the generics industry. More significant than the relative size of the firm, this acquisition marked the first serious effort by an innovative company to compete in generics after a wave of failed attempts in the 1990s. Pfizer had also recently picked up activity with its Greenstone unit and others had recently signaled that they were reassessing the sector.
- 23 According to one observer, Sandoz had focused on developing a top-three presence in specific markets, namely Germany, much of the rest of Western Europe (with the notable exceptions of the United Kingdom, Ireland, and Italy), and the United States.²⁴ This approach—which emphasized the highly localized nature of pricing and regulations—was similar to that followed historically by Teva. In contrast, Ivax, another global generics firm since acquired by Teva, had expanded into a broad number of markets, but often with smaller market shares.
- 24 Another tactic by innovative firms affected the profitability of generics. Innovative giants such as Merck, Pfizer, and Eli Lilly increasingly released their own “authorized generic” version of their products during the 180-day exclusivity period, often by licensing production rights to a competing generics company. As a result, during this 180-day period, instead of facing only a branded competitor, the first-filer also competed with the authorized generic player, who had the support of the branded firm. This practice cut into the revenues of the first-filer by an estimated 50% to 60%.²⁵ While varying significantly across products, a representative generic drug which may have held 75% market share and 30% discount off the original price without authorized generic competition might have its share reduced to 50% and discounts rise to 60%. In 2004 and 2005, several high-profile antitrust cases emerged from these practices involving both Teva and Mylan as plaintiffs; however, given no signs of dampened competition in the industry—in fact, the opposite had occurred—no one expected the practice to be curtailed. Since 2003, every major drug with revenues over \$1 billion going off patent had an authorized generic introduced onto the market.²⁶ As a result, generics companies could depend less on 180-day exclusivities

EXHIBIT 4 Competitor Information

Annual, 2005	Teva	Barr	Sandoz^a	Mylan	Watson	Ranbaxy	Dr. Reddy's
Annual Sales (\$ mil.)	5,250.40	1,047.40	4,694.00	1,253.40	1,646.20	1,117.00	469.13 ^a
Estimated U.S. generics revenues ^b	2,170.00	tbd	tbd	tba	tbd	378.00	
Operating income	1312.9	330	342.00			41.9	21.75 ^c
Employees	14,000	1,900	13,397	3,000	3,844	9,000	7,525 ^c
Market Cap (\$ mil.)	26,191.30	6,403.70	NA	4,626.50	3,747.60	3,249.00	832.70 ^a
Strategic position							
Total Rx market share in U.S. ^d	18.0%	4.0%	10.0%	11.0%	9.0%	2.0%	
Number of US Rx (June 2006, '000) ^e	391	82	212	236	195	49	
Rx growth in U.S. ^f	17.4%	-2.9%	11.7%	8.3%	7.6%	27.2%	
Number of products in the U.S.	326	75	—	140	125		
FDA approvals ^g	43	16	—	22			
FDA applications (pipeline) ^h	201	35	—	41	35	59	
Para IV applications ⁱ	47	10	—	10	1		
Profitability ^j							
Gross Profit Margin	47.20%	73.30%	—	49.60%	48.20%	53.1%	52.00%
Operating Profit Margin	25.00%	35.90%	7.30%	24.30%	14.70%	4.00%	4.40%
Return on Equity	18.80%	21.90%	—	12.80%	6.40%	9.20%	6.10%
Return on Assets	8.20%	17.50%	—	9.80%	4.80%	2.30%	1.90%
Growth ^k							
12-Month Revenue Growth	9.40%	4.90%	—	-1.70%	0.30%	-3.10%	10.40%
12-Month Net Income Growth	222.90%	74.90%	—	-31.30%	-7.60%	-63.50%	50.80%
36-Month Revenue Growth	27.70%	9.50%	—	1.40%	10.40%	11.10%	7.60%
36-Month Net Income Growth	37.70%	15.50%	—	-14.70%	-7.60%	-22.9%	-29.40%

Sources: Company 10K, 2006 Hoovers, WR Hambrecht.

^aData unavailable^bCasewriter estimates^cIMS, June 2006^dCapital IQ, accessed August 28, 2007, including acquisitions^eCapital IQ, accessed August 28, 2007. Converted at historical exchange rate (12/30/2005), Rs44.97:\$1^fDr. Reddy's Laboratories, Annual Report 2005-2006. Data is as of March 31, 2006^gDerived from Capital IQ, accessed August 28, 2007 (12/30/2005 closing share price) and Dr. Reddy's Laboratories, 6K For the Quarter Ended December 31, 2005, published September 11, 2006^hConverted at historical exchange rate (12/30/2005), Rs44.97:\$1

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for profitability and many looked to other means of protecting their margins, such as entering profit-sharing alliances with innovative firms or with each other and focusing on niche drugs which attracted less competition.

Generic Products

- 25 Generics could be roughly divided into three categories of products: commodity generics, niche or "specialty" generics, and biosimilars. **Exhibit 5** shows several stylized scenarios of revenues and margins of drugs in these different categories.
- 26 **Commodity generics** Commodity generics, typically in tablet or capsule form, were generic versions of the small-molecule pharmaceuticals that made up the bulk of innovative firms' traditional businesses and consequently comprised the largest segment of generics. Examples ranged from generic versions of antibiotics Cipro and Zithromax to painkiller Oxycontin to cholesterol-lowering drugs Pravachol and Zocor. After the expiration of a 180-day exclusivity period, the margins on these drugs were typically lower than either niche generics or biosimilars, although this varied based on the number of competitors. For example, Eli Lilly's Prozac, one of the most successful antidepressant drugs in history, had both a very large branded market and was a relatively simple compound to synthesize. As a result, once the patent and the 180-day exclusivity period had expired, 18 competitors entered the market, collapsing prices and erasing profits.²⁹
- 27 **Niche generics** Generic drugs could qualify as niche drugs if either their active molecules were difficult to synthesize or their delivery mechanism was non-standard. Respiratory drugs, for example, had patented inhalers and had to be branded and prescribed by physicians even in pharmacist-driven markets. Niche drugs could attract as few as one or even no generic version, depending on the difficulty and size of market. As expected, generic companies realized higher gross margins on these products than on commodity generics, while the capital required was greater than for commodity generics but less than for biosimilars.
- 28 **Biosimilars** The market for biosimilars was a multibillion dollar but largely undeveloped segment. Biosimilars were the generic versions of the so-called "biotech" drugs pioneered by companies such as Amgen and Genentech. The active compounds in these drugs were highly complex proteins or other large molecules that were far harder to replicate than traditional pharmaceuticals. While the worldwide market for biotech drugs was only \$29 billion in 2002, it was expected to grow to \$112 billion by 2012, a 12% annual growth rate, and take on increasing importance over the long term as the innovation in small-molecule drugs diminished and was replaced by this class of products.³⁰ Because of the complexity of the original drugs, the regulatory pathway for biosimilars was still undetermined in the U.S. and just appearing in Europe. However, the expected rewards were high as the prices of these drugs were expected to be discounted by only 10% to 20% off the branded prices, and the margins were correspondingly closer to innovative drugs than commodity generics.
- 29 Some estimated that the market could support only three to four companies competing in biosimilars because the capital and expertise required created significant barriers to entry. Predicted one industry analyst, "the companies that will be successful in [biosimilars] will be those that really have the resources to roll out a product launch. The biggest three that pharma needs to be worried about are Sandoz, Teva and Barr."³¹ Others speculated whether the biotechs themselves would expand into this business. As of mid-2006, only Sandoz had launched a major biosimilar—a human growth hormone—in Australia and Europe, and both Teva and Barr had acquired companies to enter the field (Sicor and Pliva, respectively).

EXHIBIT 5 Representative Revenues and Margins for Different Categories of Pharmaceuticals (relative to baseline of \$1 bn innovative drug)

	Patent-Protected Innovative Blockbuster	Commodity Generic in Substitute, or "pharmacy-driven," Market with Exclusivity (e.g., U.S.)	Commodity Generic in Substitute, or "pharmacy-driven," Market without Exclusivity (e.g., U.K., Netherlands)	Commodity Generic in Branded, or "physician-driven," Market (e.g., Germany, France)	Niche Generic Drug	Biosimilar Version of Biotech Drug
Approximate 12-month revenue (US\$ m)	1,000	120	10	175	490	400
Approximate gross margin (US\$ m)	930	60	4	140	392	340
Approximate operating profit (US\$ m)	300	50	3	35	196	120
Assumptions:						
Market share by volume	100%	50% first 6 mos then 35%	10%	25%	70%	50%
Discount	0%	60% first 6 mos then 90%	90%	30%	30%	20%

Source: Casswriter estimates.

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TEVA'S EARLY HISTORY

30 Teva's roots could be traced back to 1901 as Solomon, Levine and Elstein (S.L.E.), a wholesale drug distributor based in Jerusalem to serve the local population and waves of immigrants from Europe during the first four decades of the twentieth century. During the 1930s, refugees from Nazi Germany came to British-Mandate Palestine and set up several small drug manufacturing plants, including one called Teva ("nature" in Hebrew). These early immigrants tended to be highly educated, and many had been scientists, physicians, and engineers in their home country. Because Germany was the birthplace of the pharmaceuticals industry and arguably had the top universities and scientific research institutions at the time, they brought many specialized skills required to set up pharmaceuticals cottage businesses in their new country.

31 In 1945, the newly created Arab League declared a general boycott against domestic and foreign businesses operating in the Jewish portion of Palestine, which was subsequently applied to all businesses dealing with Israel when the country was established in 1948. This boycott contributed to an economic structure in which foreign direct investment comprised less than 5% of all investment in Israel through the 1970s.³³ For the nascent pharmaceuticals industry, the absence of any large foreign pharmaceuticals company spurred a domestic industry of about 70 family-owned drug distributors and manufacturers each with annual revenues of approximately \$1 million.³⁴ Together these family firms produced both the scale and, more significantly, the full portfolio of products required to serve the population of approximately 2 million people by the late 1950s. As a result, a community of chemists arose in the country with a broad set of synthesis skills, experienced in supplying drugs at a lower cost to serve the relatively poor home market. Also, since the patent-holding foreign firms would not conduct business directly in Israel, domestic firms could invoke the threat of "compulsory licensing" to pressure the patent holders into licensing the pharmaceuticals for use in the domestic market.³⁴ Compulsory licensing provisions were common in the legal codes of most countries, and could be invoked in certain situations in which good faith attempts to obtain a license under negotiated commercial terms failed for non-commercial reasons. While compulsory licensing was rarely invoked by these local pharmaceuticals companies, the threat increased their leverage to obtain voluntary licenses from the patent holders.

32 In the 1950s, SLE purchased Assia, a small pharmaceuticals manufacturing company. In 1962, Eli Hurvitz, a young employee of Assia, began the drive for consolidation of the fragmented industry. Hurvitz, born in Jerusalem in 1932, had started at Assia as a young economist in 1954. He had served as a private in the Israeli Defense Forces during the 1948 Arab-Israeli war and then obtained a degree in economics from Hebrew University. Hurvitz finished his active military service as a member of a generation of young Israelis dedicated to developing the new country. By 1962, both Hurvitz and Nachman Solomon, the head of the combined company, became convinced of the need to consolidate the industry. Solomon put Hurvitz in charge of negotiating the acquisitions. In 1963, after much discussion, they completed their first acquisition, of a company called Zori. Hurvitz reflected on his first major lesson in business:

With these private, family-owned companies, they were not ready to dilute their ownership and lose control. We had to show them that mergers produce synergies, that they make money. We needed one example to prove that the result was not small at all but an order of magnitude. Only then could we convince the rest of them.

33 In 1968, he completed his second acquisition, this time of Teva, which had been publicly listed on the Tel Aviv Stock Exchange since 1951. The combined company officially changed its name to Teva Pharmaceutical Industries in 1976. That year, Hurvitz became the chief executive of the merged entity, the largest pharmaceuticals company in Israel with revenues of \$28 million at the time.

The Billion Dollar Theory

- 34 By the early 1980s, having recently acquired Ikapharm, the second-largest remaining pharmaceuticals company in Israel after Teva, Hurvitz recognized that the company had grown as far as it could within its home market.³⁴ He hired Dr. Joseph Aleksandrowicz to head the strategic planning process for the company, which he continued to do until 1995. Aleksandrowicz recalled, "In the early 1980s, no company in Israel had any organized strategic planning. It was unheard of in the country at the time. Businesses were run more informally. Our production was best and FDA approved, we had marketing, computers, finance, and excellent, devoted people. But no one was used to creating a strategy."
- 35 Aleksandrowicz organized a two-year intensive program for the executive team, bringing in professors from leading American business schools to educate the leaders of the \$50 million company. It was during one of these sessions in the mid-1980s that Hurvitz issued a challenge that became dubbed "The Billion Dollar Theory." Said one participant at the meeting, "Eli said to us: 'We have all the capabilities of a full-sized company. If we were operating in a large western market, we could be a billion dollar company, instead of the \$50 million organization we are today. Now,' he asked us, 'how do we make that happen?'"
- 36 Hurvitz himself recalled the conversation:
- I remember in one planning meeting, I went around to each member of the executive team, asking what their growth goals were for the next year, five years. I heard 10%, 15% at the most. Everyone was thinking incrementally. I realized with that type of thinking, we would never grow to our potential. I had to break out of that thinking.
- 37 With the Billion Dollar Theory to guide them, the executive team recognized that they would have to expand beyond their home country and become the first Israeli company to enter a large, Western market. Dr. Aleksandrowicz recalled that, in addition to new markets, the group was occupied with the question of whether to be a focused company or a conglomerate and then, after choosing the focused approach— "extremely unusual for Israel at the time"—whether to be a chemicals or pharmaceuticals company:
- We decided on pharma, since it had more profits, we could collaborate with the scientific institutions in Israel, such as the Weizmann Institute, Hebrew University of Jerusalem, or the Technion, and we could export around the world. This path was so much riskier, but it also had a higher payoff if we were successful.
- 38 At the time, the company was partly owned by Koor Industries, the largest Israeli conglomerate controlled by the Histadrut, the powerful domestic trade union rooted in the socialist beginnings of the country. The board members from Koor in particular resisted this move as too risky for a company that employed so many people and served the basic health needs of much of the population. Hurvitz remembered:
- At the time, we had a \$60 million market capitalization and it would cost us \$20 to \$25 million to enter the U.S. market. Now the decision seems obvious, but those numbers made it impossible to pass through the board. So I made them a pledge: I will not ever take a risk so big that it would jeopardize the company. I will risk quarterly or yearly profits, but never the company. I have always followed that. I managed the company for 100 quarters, not afraid to bet a year but never the company.

Expanding Abroad

- 39 Despite the close cultural and trade ties between Europe and Teva's home country, the executive team chose the U.S. market first. Europe was a still patchwork of regulation and

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price controls, while the U.S. could be treated as a single market on the verge of uniform liberalization and market-based pricing. Teva entered the U.S. through a joint venture with W.R. Grace, a major American conglomerate, which gave them access to capital and contacts within the market. Chief Financial Officer Dan Suesskind said, "When we got together with W.R. Grace we said to them, 'We are willing to contribute to the partnership whatever we have, but money we don't ship over the ocean, of this they have enough in the U.S.' That's how we got to this arrangement."

- 40 Professor Elen Kohlberg, member of the board of the Teva's North America business, noted:

Here comes Teva, a nothing company from a tiny country . . . and somehow, Hurvitz manages to structure a deal where Grace puts in over 90% of the capital for 50% of the joint venture. Who else could negotiate that kind of deal? . . . Grace was so much bigger than us at the time, and yet Mr. Grace himself used to come to the office just to spend time with Eli. He viewed him as an equal. That was part of the genius of Hurvitz.

- 41 In late 1985, the Teva And Grace (TAG) joint venture acquired Lemmon, a \$20 million U.S. arm of Nattermann, a German company. From there, Teva entered the U.S. market and, just as in the Zuri deal in Israel, once it had established a foothold, sales and market share steadily grew. Hurvitz built an internal team focused on acquisitions that earned a reputation in the industry for its systematic approach and successful outcomes. Teva became the most active acquirer in the industry, sometimes paying less than one times sales for a target company and rigorously executing the integration.

- 42 By 1993, the company had reached \$502 million in revenues, halfway to its billion dollar goal, and North America had overtaken Israel as the largest contributor to the business. Teva continued to expand throughout the 1990s and 2000s, fueled by a series of acquisitions in North America and Europe (see **Exhibit 6**), and passed the billion dollar revenue mark in 1997. The geographic make-up of Teva's revenue changed dramatically as the company expanded. Israel accounted for the majority of the company's revenue until 1991, but that share had fallen to just 6% by 2004. During that same period, the North America share of revenue rose from 33% to 64% while the contribution from Europe and the CIS increased from 9% to 26%.

Developing Competitive Advantage

- 43 Over time, Teva became one of the largest suppliers to the growing segment of national pharmacy chains in the United States. In the mid-1980s, when Teva entered the U.S. market, the industry was dominated by wholesalers and distributors which had long focused on serving mom-and-pop pharmacies. Teva filled a vacuum for these national chains, enabling them to reduce their own internal costs by sourcing much of their formulary from a single company without use of a middleman. Teva provided not only a broad scope of products, but also inventory management, volume-based discounts and pricing bundles, services less valuable to the mom-and-pop but very important to the cost-conscious chains. Teva also kept its focus on low prices, acknowledging the commodity-like nature of the industry. Hurvitz reflected,

Throughout the 1980s, everyone kept saying, "The Chinese are coming!" Everyone was terrified of this situation back then. So, we had to neutralize price as an issue for us. We spent a lot of time on our manufacturing and business model to ensure this, and always, always guaranteed the lowest price to our customers. If our competitors lowered prices after the contract was signed, we would give our customers credit. We were willing to forego part of our income in the short term for the long term. We knew back then that he who keeps market share will be the one who makes money in this industry.

EXHIBIT 6 Teva Acquisitions from 1985 to 2005

Date	Company Acquired	Location	Transaction Value (USD, M)	Value/Sales	Target Implied Price/Earnings	Teva Price/Earnings
Jul-05	Ivax	United States	7,367	3.65	39.5	18.9
Aug-04	Ocoron	Italy	85	2.33		
Oct-03	Sicor	United States	3,401	6.49	23.8	23.5
	Honeywell Fine Chemicals	Italy	168	N/A		26.29
Jun-02	Bayer Classics	France	86	N/A		27.16
Dec-99	Novopharm	Canada	258	N/A		38.13
Aug-99	Copley	United States	220	1.77	39.7	33.14
May-98	Pharmachemie	Netherlands	87	N/A		26.45
		United Kingdom				41.41
Aug-96	APS/Berk	United States	53	0.81		
Jan-96	Biocraft Labs	Hungary	296	2.12		38.97
Nov-95	Biogal		25	0.36		33.13
	Proclintex and					25.38
Mar-92	GRY-Pharm	Italy, Germany	23	N/A		
1988	Abic	Israel	27	N/A		
1985	Lemmon	United States	21	N/A		

Source: Windhamer's Strategic Intelligence Systems, Company 20F, Thomson Financial, Securities Data, Capital IQ.

44 This philosophy stayed with Teva in the subsequent years. According to HersHKovitz, "No one takes market share from Teva—no one. In the past, they have slashed their prices like nobody's business. This is a rule for the Indian companies: if you go into a Teva drug, you lose money, as simple as that."

45 Teva also sought to gain advantage through rigorous execution, including filing ANDA applications earlier and with fewer revisions than its competitors, backward integrating into active pharmaceutical ingredients, and efficiently managing its supply chain. As a result, Teva was able to sustain a large pipeline of Paragraph IV challenges as well as a broad portfolio of commodity generics, an elusive balance for its competitors.

Developing an Innovative Business

46 In the early 1980s, Teva decided to enter the innovative drug market, a move dubbed as "sheer chutzpah" by Hershkovitz. By 2006, Teva's strong relationship with Israeli academic institutions yielded 150 to 180 proposals for new drugs per year. They had launched three drugs: two in partnership with Weizmann, including their blockbuster drug, Copaxone, in 1996, which became the leading treatment for multiple sclerosis. Teva relied on these external institutions for drug discovery, in contrast to Pfizer or other companies producing innovative drugs who had large internal basic research divisions. As a result, Dr. Irit Pinchasi, the VP of global innovative R&D, estimated that Teva's drug development cost for Copaxone amounted to approximately one-sixth to one-fourth the \$1 billion typically required to bring an innovative drug to market.⁴⁷

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Mergers & Acquisitions

- 47** Since 1985 Teva had executed 14 transactions together worth over \$12 billion, more than any other generics company, including Sandoz. It had built a reputation for successful mergers and fair treatment of employees, in part arising from the small community within Israel in which the consequences of treating employees poorly could be severe, and because it reflected deeply held values of Eli Hurvitz.

- 48** Many acknowledged the need for consolidation among generics companies. In the U.S., the top four firms controlled less than 50% of the market, the next six together controlled 20%, and none of the more than 40 firms in the remaining tail controlled more than 2%.¹⁵ As Hurvitz stated,

The market needs consolidation, globally. The more commoditized the market, the more this is true. And in this industry, the smaller players are the price leaders . . . Mathematically we have a problem: we are already large. Today we are 20% of the [U.S.] market. How far can we go?

- 49** In 2002, Israel Makov succeeded Hurvitz as CEO, who, at 70 years old, remained in place as chairman. This event marked the first leadership handover within the company since 1976. The company continued its string of acquisitions, however. In 2005, Teva acquired Scler which, at \$3.4 billion, was eight times the deal size of its previous largest acquisition. Scler offered not only additional scale, but also expansion into new customers, products, and technologies, selling injectable liquid products directly to hospitals rather than more traditional tablets to pharmacies. Some hailed the acquisition as an opportunity to expand and diversify away from commodity generics, particularly into biosimilars and the lucrative injectables business. Others cautioned that the businesses were too different and that the opportunity cost of choosing Scler over other businesses had been high. Said one observer, "Focus had been the key to Teva's success over the years, during periods when other companies fell down trying to do too much. Scler changed too many variables at once."

- 50** In 2005, Teva acquired Ivax for \$7.4 billion, a move viewed positively by analysts for a variety of reasons. Some saw it as a tactical acquisition to gain access to Ivax's very strong first-to-file Paragraph IV pipeline in the U.S., which included generic Zocor and Zolofit (two of the largest blockbusters in history), at a time when Teva's own pipeline had softened. Others viewed the acquisition as more strategic, with Ivax's strong positions in global markets where Teva had little presence, particularly Latin America and Eastern Europe, as well as their innovative pipeline and niche generics in therapeutic areas new to Teva. Still others viewed the innovative and niche businesses positively, but were cautious of overexpansion into many small physician-driven markets.

Supply Chain

- 51** By initially limiting its markets to the U.S. and Israel and only slowly adding in new markets, Teva had maintained a rigorously low-cost culture and achieved greater scale benefits in its supply chain than any of its competitors. Said Eli Shohet, vice president responsible for the Ivax integration and the Central and Eastern Europe region:

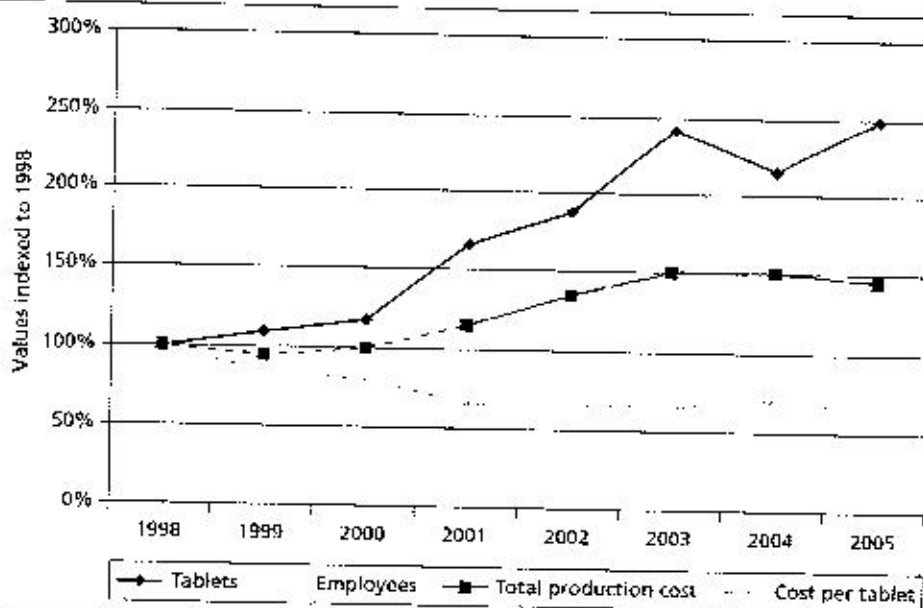
The bottom line is that we have scale advantages that cannot be matched by other companies at this time. Compare Ivax before the merger and Teva. In Teva, we have two plants in Israel that are currently capable of eight billion tablets and one in Canada with the same scale. One hatch at Teva would have required five to six runs at Ivax, all in different locations. This is so much more expensive, and this is how most companies are set up. With our size, we can also source raw materials on a much larger scale than our competitors. You cannot just look at labor costs. First of all, they are not the only input and second of all, we are much more productive and capital intensive. And for labor intensive processes, we have operations in India.

- 52 Teva reconfigured its supply chain every several years since the early 1990s and after every major acquisition. The most recent integration with Ivax had been particularly challenging, as Ivax and Teva organized their worldwide operations very differently. Reflected Shohet,

The culture of the two companies is the same, but the business model is different. Since 1995, Teva has operated as a global company. We localize the management and marketing in each region while having a global backend in R&D, manufacturing and APIs [active pharmaceutical ingredients]. The Ivax business model was an international company. It operated as a series of independent companies with very little cross border interaction.

- 53 The backbone of Teva's supply chain was managed through several centers of excellence located globally to take advantage of differences in local labor skills and costs, tax provisions, and intellectual property regulations. The supply chain started with active pharmaceutical ingredient (API) production, a step which many of Teva's competitors at least partially outsourced, often to Teva. Teva's API division had sold \$1.1 billion of ingredients in 2005, approximately evenly divided between internal and external use, and was one of the world's largest third-party suppliers of APIs. Once the APIs were produced, they were sent to pharmaceutical manufacturing facilities. The two largest of these facilities were in Israel, which primarily supplied the U.S. and Israeli market and had a capacity of 16 billion tablets, and in Hungary, which primarily served Europe. Teva estimated that it would produce 36 billion tablets in 2006. Teva reported unit-cost reductions of 30% in 2001-2005 due primarily to scale effects (see Exhibit 7).³⁹ Once the tablets were produced and packaged appropriately, they were shipped to their various markets and distributed locally. See Exhibit 8 for a map of Teva's Israeli operations. Given the security risk associated with Israel's political situation, redundancies in the supply chain and extensive disaster planning had been conducted to mitigate disruptions associated with potential conflict within the country.

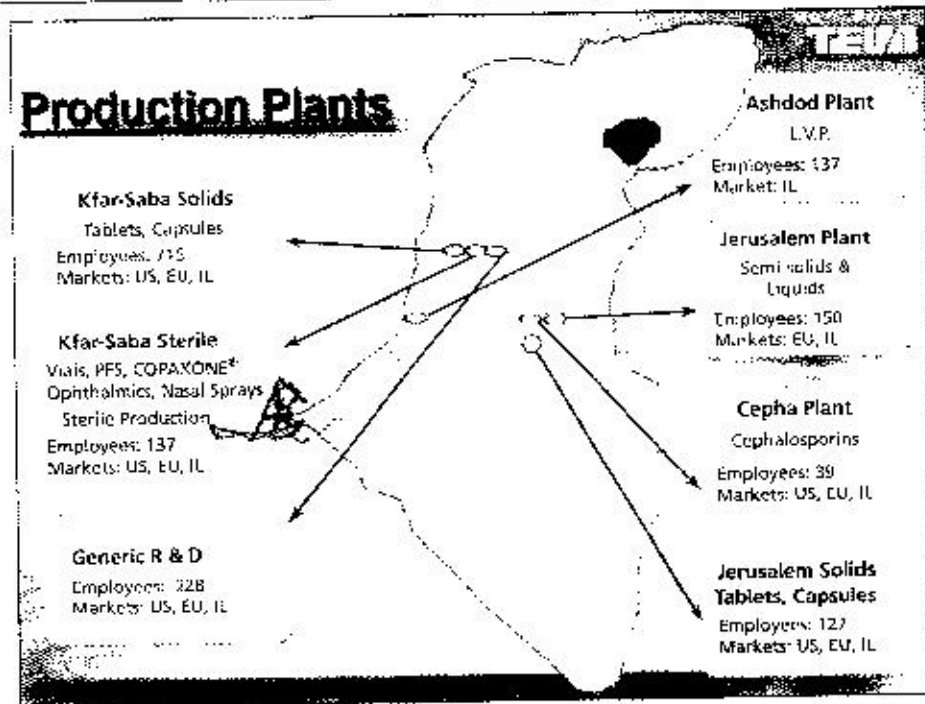
EXHIBIT 7 Teva Cost and Output Trends (1998 to 2005)



Source: Teva.

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EXHIBIT 8 Teva Israel Production



Source: Teva company documents

TEVA IN 2006

Generic Markets

- 54 United States** By the middle of 2006, Teva controlled approximately 18% of the base U.S. generics market by number of prescriptions (see **Exhibit 9**). Its total pipeline as of August 9, 2006, including the 180-day drugs, was 148 drugs products with branded sales of over \$84 billion.⁵⁴ This segment formed the core of Teva's business, and some analysts expressed concern about the systemic erosion of prices in the U.S. market. The combined Ivax-Teva pipeline of 180-day exclusivities in 2006 was the largest in the industry. As of August 9, 2006, the company had 46 first-to-file Paragraph IV applications, covering drugs with \$35 billion in branded revenues. From January through August 31, 2006, Teva had launched four drugs with exclusivities, including generic Zocor in June, the largest generics launch in the history of the industry covering branded sales of \$4.4 billion. From January 1, 2004 through May, 2006, Teva had filed 24 Paragraph IV challenges compared to eight for Sandoz.⁵⁵ However, this market was tightening as more companies vied for a fixed number of exclusivities.
- 55 Europe** Prior to the Ivax acquisition, Teva had focused on the pharmacist-driven markets in the U.K. and the Netherlands, as well as several other larger markets which showed signs of potentially moving to a pharmacy-driven model. It had maintained either low or no presence in the markets that remained dominated by physician-driven regulation, most notably Germany and Japan.

EXHIBIT 9 Teva Total Generics Prescriptions

Total Prescriptions in U.S. (June 2006)					
All Pharmaceutical Companies			Generics Only		
Company		Growth	Company	Share	Growth
Teva USA	393,014	17.3	Teva USA	18%	17.4
Pfizer	314,200	-9.1	Mylan	11%	8.3
Novartis (without Sandoz)	292,317	8.4	Sandoz	10%	11.7
Mylan	239,045	7.8	Watson	9%	7.6
Watson	195,060	7.6	Mallinckrodt	5%	23.9
Merck	137,545	9.9	Actavis	4%	-1.2
GlaxoSmithKline	128,982	3.0	Barr	4%	-2.9
AstraZeneca	114,789	8.3	Par	3%	-2.8
Mallinckrodt	103,874	23.9	Qualitest	3%	7.2
Actavis	89,022	-1.2	Ranbaxy	2%	27.2

Source: Teva, primary; IMS, June 2006

EXHIBIT 10 Teva and Ivax Geographic Mix, 2004

Teva ^a		Ivax ^b	
North America	3,059	United States	860
% total	64%	% total	46%
Europe and CIS	1,245	Europe	704
% total	26%	% total	37%
Israel	285	Latin America	316
% total	6%	% total	17%
Other countries	210	Other countries	0
% total	4%	% total	0%
Total	4,799	Total	1,880

Source: WR Hambrecht.

^aTeva 2004 20F^bWR Hambrecht estimates

- 56 Europe comprised approximately 30% of Teva's 2005 revenues. Ivax gave Teva presence in the growing markets of the Czech Republic, Poland, Russia, and Slovakia (see Exhibit 10). Within Europe, Hungary, the U.K., and the Netherlands comprised approximately 75% of Teva's revenues, reflecting Teva's strength in pharmacist-driven markets and the legacy of Biogal, the company's acquisition in Hungary. Germany and France, the two largest physician-driven markets, together comprised slightly more than half of the remaining European revenues. Analysts differed on how Teva should approach these and other physician-driven markets. Teva could wait for the markets to adapt to a structure closer to the pharmacy-driven model in which Teva excelled. At the same time, other companies were already aggressively expanding into continental Europe, establishing dominant positions that could become difficult to displace later.

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- 57 Rest of world** In Japan and other Asian markets, Teva—like most other generics companies from outside the region—had adopted a wait-and-see strategy and had little presence. Ivax brought to Teva the leading presence in Latin America, which had contributed approximately 25% to Ivax's 2004 profits and was growing quickly.

Other Products

- 58 Niche products and biosimilars** After the Ivax acquisition, Teva reorganized its internal operations and set up a separate specialty division to focus on niche products (such as hospital and respiratory drugs) and biosimilars. Teva expected \$400 million in revenues from its respiratory franchise in 2006, growing to \$1 billion to \$2 billion by 2010.⁴⁴ It had not launched any significant biosimilars products in 2006, but expected this segment to be a high-growth area. However, some questioned whether Teva had focused too heavily on the U.S. market, which was bogged down in a regulatory impasse that was estimated to take five years or more to resolve. In contrast, Sandoz had focused more on Europe, working closely with the European regulatory authorities and had at least one marketed drug.
- 59 Innovative pharmaceuticals** Copaxone had been Teva's first innovative drug, and had become the top treatment for multiple sclerosis in the world with worldwide total sales of \$1.2 billion in 2005. It continued to grow at an annualized rate of 22% in 2006, compared to a combined rate of 13.5% for its competitors,⁴⁵ and had become an important contributor to Teva's overall profits. The cost structure for Copaxone differed from a typical innovative drug. In addition to lower research and development costs, sales and marketing expenses—typically two to three times the cost of R&D at large innovative firms—were lower for Copaxone, given the limited population of prescribing physicians. Furthermore, Teva had partnered with Sanofi-Aventis through 2008 to manage the sales and marketing of the drug, thus off-loading much of these costs from Teva. Most analysts estimated that Sanofi-Aventis passed on 50% to 60% of the revenues back to Teva. See **Exhibit 11** for an approximate breakdown of Teva's revenue between 2003 and 2005.
- 60** Azilect, a treatment for Parkinson's disease, had been released to the market in mid-2006. Dan Suesskind noted the importance of bringing this second drug to market: "At least [Azilect] showed that Copaxone was not a one-off. Having two marketed drugs is almost more important than having a pipeline." Teva also had a pipeline in other therapeutic areas with estimated potential sales of \$6 billion by 2015.⁴⁶ Outside analysts estimated that this

EXHIBIT 11 Teva Estimated Revenue Breakdown, 2003–2005

	2005	2004	2003
Net Sales	5,250	4,799	3,276
Copaxone (@55%)	647	515	396
API	524	501	371
Other	23	22	20
Generics in U.S.	2,166	2,173	1,399
Generics in EU and ROW	1,890	1,589	1,091
Total generics sales	4,056	3,761	2,489
Number of generics prescribers in U.S.	252	270	N/A

Source: Company 20F and case writer estimates

number could, in fact, be much higher and that, given the superior economies of innovative products, the relative proportion of innovative to generic drugs in Teva's revenue mix, would steadily increase during the next decade. Others wondered whether four or five different therapeutic areas⁶¹ was too much for Teva's limited research budget and limited experience bringing drugs to market.

Innovative vs. Generic

- 61 In 2006, Teva reported R&D expenses at an annualized rate of \$500 million or approximately 6% of sales. Allocating resources between innovative and generics areas was one of the company's main challenges. The lead time for innovative drug development was 10 to 15 years, while generics development was three to five years, and the act of selecting and executing projects required very different skills and information. Reflected Dr. Ben-Zion Weiner, the head of Teva's research and development group:

It is interesting how these two animals live under the same roof. On the one hand, we have low-risk products in generics, and then we have Copaxone and Avilact. The same person manages both and is responsible for dividing the resources. This is a very tricky decision making process. How do you trade off, say, investing in 10 low-risk generics drugs versus one high-potential innovative drug? This is a big part of our challenge.

- 62 Within the generics R&D division, Weiner's group had worked to create "an ANDA factory." Over the past decade, Teva had filed and won the greatest number of 180-day exclusivities in the industry, earning a reputation for quick ANDA filings and aggressive patent litigation. "Of course," said Dr. Weiner, "fifteen years ago, we were the entrepreneurs in this area. Since then, we have been studied by others and the gap has shrunk."
- 63 The innovative R&D group, on the other hand, had a different set of challenges. Said Weiner, "We are so small compared to the big guys. The consolidated research and development budget of the top 10 innovative firms is \$45 billion. What can we do with a budget of [a few hundred million] against that? And that's just the top 10, the total budget of the industry is much bigger." In this context, the Teva team decided to leave the original research to external institutions, and to build research franchises in areas that did not require mass marketing to the general public and family doctors. With the addition of Ivax's research arm and existing pipeline, Pinchasi estimated that, by 2010, Teva would have a sufficient pipeline theoretically to launch one new innovative drug per year, in comparison to five per year of leading pharmaceuticals companies such as Pfizer.⁶² Said HersHKovitz, "[Teva's innovative R&D group] is running way, way under the radar right now. They are currently running over 10 phase 2 trials, in addition to their phase 3 trials. And every month it seems as if we discover another clinical trial that they are involved in through equity in a startup."
- 64 Other companies, particularly Novartis, were tackling the same issue although from different corporate roots. Sandoz had achieved operating margins of only 7.3% in 2005 compared to 25% for Teva, and some employees commented on the issues with running a generics division within an innovative company. "In Novartis, if you sell the [branded] product one month later or not it doesn't make a big difference, because there is no other company to sell it," says Bodri Tokar, Sandoz's top executive in Turkey. "But as a generic company I have to be first because there are many companies that can sell the same product. . . . The way of thinking is very different." Roche, another large innovative firm, had also considered entering the generics business three times over the last decade, but decided against it based on their belief that pure generics companies would always be able to under-price Roche. Hurvitz held similar views, saying, "It is very easy to manage a generic company when you are poor. It becomes very complicated when you are rich. It is impossible for

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a rich company to act poor. As long as we remember this equation, and we do not become bureaucrats, and as long as we fight the fat culture, we will succeed.”

- 65 Roche, like the other companies, also decided that it was too difficult to manage patent creation and challenging under one corporate umbrella.⁴ This issue arose for both Novartis and Teva. Sandoz could not challenge any Novartis patents, and filed far fewer Paragraph IV challenges than Teva. On Teva’s side, as they released more innovative drugs to the market, they anticipated greater challenges by other generics firms to these drugs. Responded Dr. Pinchasi to how they will manage these dual missions: “That will be interesting, no? We’re now trying to learn what you have to do to make things hard for generic drug makers . . . After all, we know better than anyone how to challenge patents, but there’s no guarantee we’ll succeed. Yes, there are quite a few companies that would like to turn the tables on us, and challenge our patents.”⁵
- 66 Many were watching whether either Sandoz or Teva could manage both businesses effectively under one corporate umbrella, particularly as they came from different roots but both sought growth in similar areas: generics sales in global markets, biosimilars, and niche innovative drugs.

CONCLUSION

- 67 After years of tremendous success competing against richer, Western companies, Teva was now the reigning incumbent in an increasingly competitive industry. New low-cost players were coming in behind them, having learned from Teva’s success and hungry to capture a share of the growing market. The innovative firms had also finally woken up—vigorously protecting their hard-earned patents while also encroaching on the generics market. In front of Teva lay the complex world of global markets for generics, as well as the innovative drug market, both of which were large and growing but did not necessarily play to Teva’s historical strengths. How should Teva grow in the next ten years? Should it focus on consolidating in the U.S. and other substitution-oriented generics markets, on further expanding into the global branded generics markets, or on gradually turning itself into a more specialized generics or even an innovative firm? Alternatively, did it need to focus on all three areas to succeed, and if so, could it manage such diverse goals under one roof?

END NOTES

¹ “Plummeting Teva stocks affect every household,” Yedioth Ahronot, June 25, 2006.

² Alternately, the company could be viewed as listing in 1951, accounting for an antecedent company.

³ “Teva/Tvax: Generics’ Answer to Big Pharma,” *Iskra*, September 2005.

⁴ Dan Suesskind, personal communication; Ranbaxy company documents.

⁵ Casewriter estimates based on published financial reports and IMS data.

⁶ This section has been adapted from “Strategy in the Twenty-First Century Pharmaceutical Industry: Merck & Co and Pfizer Inc.”, IBS Case N2-707-487.

⁷ IMS Health, “Global Pharmaceutical Sales, 1998-2005,” IMS Health Company Web site, February 27, 2006, cited in IBS Case 707-487, “Strategy in the Twenty-First Century Pharmaceutical Industry: Merck & Co. and Pfizer Inc. (RC Strategy)”.

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- ² Henry Grabowski and John Vernon, "Longer Patents for Increased Generic Competition: The Waxman-Hatch Act After One Decade," *Pharmacoeconomics*, Vol. 10, Supplement 2, (1996): 110-123; Anita McGahan, Dale O. Cox, Greg Kuller and John F. McGuire, "The Pharmaceutical Industry in the 1990s," Harvard Business School Case No. 796-058, Rev. July 18, 1996.
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- ⁴ Bradley Weber, "The Pharmaceutical Industry," cited in HBS Case 707-487, "Strategy in the Twenty-First Century Pharmaceutical Industry: Merck & Co. and Pfizer Inc. (RC Strategy)".
- ⁵ Henry Grabowski, John Vernon, and Joseph A. DiMasi, "Returns on Research and Development for 1990s," cited in HBS Case 707-487, "Strategy in the Twenty-First Century Pharmaceutical Industry: Merck & Co. and Pfizer Inc. (RC Strategy)" New Drug Introductions," *Pharmacoeconomics*, Vol. 20 Issue 15 (Supplement 3), (2002): 11-29, via EBSCO, accessed September 2006, cited in HBS Case 707-487, "Strategy in the Twenty-First Century Pharmaceutical Industry: Merck & Co. and Pfizer Inc. (RC Strategy)".
- ⁶ United States from 1963 to 1999," *Clinical Pharmacology and Therapeutics*, Vol. 69, No. 5, (2001): 286-296; Joseph A. DiMasi, Ronald W. Hansen, and Henry Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics*, Vol. 22, Issue 2, (March 2003): 151-185; "Personalized Medicine: The Emerging Pharmacogenomics Revolution," *PriceWaterhouseCoopers*, February 2005, <http://www.pwc.com/techfuturecast/pdfs/pharmaco-wh-x.pdf>, accessed September 2006. Another study, which included commercialization costs, put the figure of bringing a single new drug to market at about \$1.7 billion; see Peter Landers, "Cost of Developing a New Drug Increases to About \$1.7 Billion," *The Wall Street Journal*, December 8, 2003, p. B4, via Factiva, accessed September 2006, cited in HBS Case 707-487, "Strategy in the Twenty-First Century Pharmaceutical Industry: Merck & Co. and Pfizer Inc. (RC Strategy)".
- ⁷ "Mixing Medicines: Betting \$10 Billion on Generics, Novartis Seeks to Inject Growth," *Wall Street Journal*, May 4, 2006.
- ⁸ Remarks by Lester M. Crawford, Acting Commissioner of Food and Drugs to the Generics Pharmaceutical Association, 26 February 2005, and WR Hambrecht estimates.
- ⁹ Dr. Joseph Aleksandrowicz, personal communication.
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- ¹¹ Ranbaxy Laboratories, Corporate Presentation, May 2006.
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- ¹⁷ Ranbaxy website, accessed August 28, 2006.
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- ²² Roubi, "Generic Tide is Rising," *Chemical and Engineering News*, Volume 80, Number 38, CEN:AR 80 38 pp. 37-51.
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