PART 1 CASES

Case 1-1: Pfizer and the Challenges of the Global Pharmaceutical Industry*

Introduction—Pfizer

In the beginning of 2007 Jeffrey Kindler, Pfizer's new chairman, pondered over the company's stagnating performance. Growth had slowed down recently and the company could not achieve its annual goals. Having just joined the company, Kindler still had to spend time to learn about the pharmaceutical industry and Pfizer's strategic position. His previous leadership of McDonald's had proven to be a success story. Now the switch to Pfizer proved to be a challenge as Pfizer's shareholders continued to be disappointed with the company's recent developments.

Not only had revenues declined but also the blockbuster drug called "Lipitor" was losing its momentum. Lipitor is a cholesterol-lowering drug that had contributed US$13 billion in sales. This comprised 40% to total company's profit. In December 2006, Pfizer faced a setback in developing "Torcetrapib" which should have been the "blockbuster" successor for Lipitor. The research program for "Torcetrapib" was stopped due to significant concerns regarding human safety. Drastic side-effects had risen unexpectedly resulting in financial investment losses for Pfizer.

The general changes and industry developments worried many pharmaceutical managers. One area of concern was the role and influence of pharmaceutical firms on price setting. In 2005 the German government demanded price reductions across the board for all types of drugs. For example, the German government wanted to reimburse the medical expenses of Lipitor patients up to a certain amount. If the price of Lipitor was further reduced by 38%, then German patients could receive full reimbursement for their purchase cost. Previously, the German government had already negotiated the lowest possible price for Lipitor. This dual step price reduction had a drastic effect on the potential earnings of Pfizer.

Price pressures existed not only in Germany. On the 1st of January 2005, the Pharmaceutical Price Regulation Scheme ("PPRS") came into effect in the United Kingdom. The PPRS's goal was to set profit boundaries on all types of medicines. Kindler's colleague Tom Mckillop, the CEO of AstraZeneca, spoke of an "Extortion like" situation.[1] Felix Raeber, head of European media relations for Novartis referred to a situation where the pharmaceutical companies were "without control."[2]

In addition, managers were also worried about the public recognition and evaluation of the activities of pharmaceutical firms. Normally the efforts of drug companies to develop new medicines were accepted favorably by the general public. However, pharmaceutical firms had a negative image during the previous few years. A survey in the US showed that only 14% of the respondents had a very positive impression of the pharmaceutical industry. Fifty percent of the respondents had a bad impression. This implied the pharmaceutical industry had a reputation similar to oil and tobacco companies. Historically, the pharmaceutical industry had been one of the most profitable and high margin industries for many years. Could the industry continue to sustain such trends given ongoing changes?

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*This case was written by Dr. Phillip Nell,[1] Center for Strategic Management and Globalization at Copenhagen Business School and Dr. Björn Ambos,[2] Institute for International Marketing and Management at Wirtschaftsuniversität Wien. It is intended to be used as the basis for class discussion rather than to illustrate either effective or ineffective handling of a management situation. The case was compiled from published sources and generalised experience.

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Exhibit 1 Development of Total Expenditures on Health Per Capita in USD Purchasing Power Parity

	1960	1970	1980	1990	2000	2001	2002	2003
North America	136	326	928	2.245	3.546	3.826	4.093	4.355
Europe	69	202	641	1.165	1.934	2.075	2.253	2.409
Japan	30	149	580	1.116	1.967	2.082	2.138	2.249
Asia/Pacific	94	232	455	887	1.594	1.725	1.842	1.949
Latin America	—	—	—	306	506	548	578	608
OECD average	79	214	639	1.180	1.961	2.106	2.275	2.427

Source: OECD Health Data 2006.

The Pharmaceutical Industry

Global health expenses increased steadily during the last decades. In 2003, the average per capita spending on health care in OECD countries amounted to US$2,400. (Refer to Exhibit 1.) The health expense measured as a proportion of gross domestic product rose from 7.8% in 1997 to 8.8% in 2003.

Currently, medicines comprised 18% of global health expenses with a tendency to increase in the near future. The reasons for this were numerous. First, the proportional increase of the ageing population in most countries led to a larger demand of medicinal usage (Exhibit 2). Second, there was a need to develop innovative and expensive medicines during the last few decades especially for new strains of diseases such as cancer and AIDS which had previously no cure. In this case, differences among countries could be observed due to differences in consumption patterns, medicine prices as well as income levels. (See Exhibit 3.)

During recent years medication expenditures had risen faster than total health spending. The global medicine market amounted to US$643 billion in 2006. (See Exhibit 4 below.) The medicine product market was segmented based on various categories depending on the chemical composition, safety and frequency of usage. The first category was whether a prescription was required. Prescription drugs can only be given out by doctors and pharmacies.

Exhibit 2 Share of Elderly People (≥65) of the Total Population in %

	1960	2003
UK	12	16
US	9	12
Italy	9	19
Japan	6	19
OECD	9	14

Source: OECD Health at a Glance, OECD Indicators 2005.

Exhibit 3 Per Capita Expenditures on Pharmaceutical Products in USD for Selected Countries

Land	Per capita expenditures on pharmaceutical products in USD purchasing power parity in 2003
US	728
France	606
Germany	436
Italy	498
Sweden	340
Poland	225
Mexico	125
Turkey	112

Source: OECD Health at a Glance, OECD Indicators 2005.

The second category was called over-the-counter-drugs or "OTC." These are medicines purchased without a prescription. This category also includes food supplements and vitamins. The latter were not classified as medicines and were sold in pharmacies and, in the US, in supermarkets. The OTC-market was comparable to the consumer goods markets.[3] In the prescription drug market, a distinction was drawn between generics and branded drugs. A generic (multiple generics) was a medicine that had the same active agents as a branded drug. In other words, a generic was a copy of branded drug that patent had expired. Generics are marketed only the after the patent expires.

Health systems in Europe and in the US were fundamentally different. In the US, there was no public health insurance to reimburse patients for the costs of medicines completely or partly. The large majority of the Americans were, therefore, privately insured. The US government seldom got involved with price regulation. Consequently, the US market offers the highest prices worldwide and was by far the most important market for the pharmaceutical industry.

In most European countries there was compulsory health insurance supported by the state and accessible for the whole population. A large portion of the drug expenses were paid by the state. In 2001, the share of public

Exhibit 4 Development of the Global Pharmaceutical Market

Year	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Total global sales (in US$ billions ex-manufacture price)	298	334	362	387	427	498	559	601	643	712	775
Growth rate (in % at a constant US$)		14.5	11.7	11.8	10.6	10.4	8.0	6.8	7.1	6.4	5.3

Source: IMS Health (2009).

spending to total spending added up to 72% on average in OECD countries. The other 28% of the expenditures were funded privately by private insurance or by patients. This average, however, did not show the significant disparities between some countries. In addition, there were considerable differences relating to the share of public and private financing sources within medicine expenditures (Exhibit 5). On average 60% of medication expenses in OECD countries were financed publicly.

Based on this, the national health systems were the basic principal payer for medicines in Europe. Considering the increasing health care spending and tight national budgets, the European governments were considerably more active in price regulation. To achieve this, the governments used various measures. One of these measures was setting fixed prices in negotiations between the state and the manufacturer. This involved lengthy price and reimbursement negotiations which could delay product launch significantly.

Governments could also set prices by so-called "referencing." The price of drugs were adjusted to the prices of other countries. Also "internal referencing" was employed where products with similar therapeutic effect were grouped together and a relatively lower all-in price is determined for every group. The reimbursement system was then aligned so that the patient must pay for the drug himself if the drug price was higher than the reference price. Other measures taken by governments were "all-in price markdowns" that were demanded from all manufacturers and the limitation on profit margins for certain products such as the PPRS system in the UK.

Despite the mechanism of "referencing," the different price regulation schemes led to considerable price differences within the European markets. For products that entered the market in Europe in 2000, a price range of 30% over and under the EU average price existed. This price control, combined with the free transportation of goods within the EU, resulted in parallel imports during the previous years. This led to forgone profits of approximately three to four billion Euros for the pharmaceuticals industry.

Governments influenced not only the price, but also the demand through the reimbursement system of their respective health care institutions/authorities. Patients often could only get their medicine expenses repaid if the drug was recognized as reimbursable by their national health care system. Many countries established so-called positive lists where all products on the list were reimbursed, negative lists where all products on the list were not reimbursed, or both. When a prescription drug was not reimbursed, the demand for this drug was automatically limited. Premium prices and the reimbursement of costs were mostly achieved by medicines that brought therapeutic advantages: "First-in-class products" and highly

Exhibit 5 Public and Private Spending on Pharmaceuticals Per Country in % of Total Spending

	Public spending	Private spending
US	21%	79%
Canada	38%	62%
Switzerland	66%	34%
Norway	59%	41%
Iceland	58%	42%
UK	64%	36%
Sweden	70%	30%
Spain	74%	26%
Slovakia	83%	17%
Portugal	66%	34%
Poland	41%	59%
Netherlands	57%	43%
Luxembourg	83%	17%
Italy	49%	51%
Ireland	86%	14%
Hungary	63%	37%
Greece	74%	26%
Germany	75%	25%
France	67%	33%
Finland	54%	46%
Denmark	49%	51%
Czech Republic	77%	23%
Belgium	45%	55%
Austria	70%	30%

Source: OECD Health Data 2006.

innovative biotechnology products are examples of such medicines.

In most health care systems, doctors were relatively free to determine the treatment and medication. Usually they could choose between different substances and between branded medicines versus generics. While many EU countries fostered the prescription of generics which were bioequivalent to the branded drugs, doctors could still often intervene and push through the choice for the branded drug. Therefore, in some countries doctors could only mention the active ingredient in the prescription and not the brand name.

When choosing medication, doctors tended to be extremely loyal and frequently choose one particular product that they felt provided a positive feedback for their patients. Often, these were the branded drugs. The market power of expensive branded drugs was sustained by the fact that in most countries there were no defined regulations on cost cutting or preferences for generics (such as the above-mentioned rule to prescribe only active ingredients), and that neither patients nor doctors themselves had to pay for the branded drug as these were subsidized by the governments in Europe. Usually, however, doctors become sensitive to price increases when the patient himself had to bear a large part of the costs.

The marketing activities of pharmaceutical companies were focused on the doctors, who served as key decision makers. Approximately 70% of the total administrative and marketing costs were spent on direct contact with doctors. This was roughly US$13,000 per year per doctor. Sales representatives were the main communication channel between pharmaceutical firms and doctors. Therefore, many firms had invested extensively in the number and training of their sales personnel. Meanwhile there were signs of "over marketing." Doctors were complaining about the numerous and extensive sales pitches by sales representatives. Many firms, however, did not want to reduce their sales force unless the competition did the same. The firms were trapped in a "marketing and sales arms-race" as phrased in the magazine *The Economist*. Most market participants were aware of the substantial effect this had on their profitability due to the high overhead, administrative and marketing costs for pharmaceuticals firms. Such expenses were twice the research expenditures. It was also claimed that corrupt practices were sometimes used in order successfully bring selective products into the market.

The role of patients in the buying process had increased over time. Traditionally doctors were the only information source for patients, even though they spent less and less time with their patients. This was related to the increasing trend of self-medication. For pharmaceutical firms this development was dangerous, because in Europe all direct marketing targeted at patients was prohibited.

Another trend was the rise of alternative and complementary medicines and treatments. In Africa, Asia and Latin America, traditional medicine played an important role in health care. In Western markets, many of these treatments were scientifically controversial where the medical effects were unclear or the side effects relatively strong or unforeseeable. In the largest European markets, the US and Japan, alternative medicines were often used as complementary therapy to a more conventional treatment. The additional costs were often paid by patients themselves.

Development of Drugs and the Patenting Process

The pharmaceuticals industry was, similar to the oil industry, a "self-liquidating" industry. Both had to continually develop new products, i.e. locate oil- and gas fields to fill their pipelines. Both involved long gestation periods of development before a product was launched. In the pharmaceuticals industry, the product development phase took around 10 to 15 years and there were signs that the "simple discoveries" had been made by the 2000s (Exhibit 6).

The development process started with identifying a "goal" in the human body; for example, a protein against which the medicine can act. Then, the different chemical properties within the formula (preparations) were tested

Exhibit 6 Duration of Research and Development Phases (in years per time period)

Time Period	Pre-clinical Test Phase	Clinical Test Phase	Patent Approval Phase
1963–1969	2.6	3.1	2.4
1970–1979	2.4	7.1	2.1
1980–1989	2.3	9.0	2.8
1990–1999	3.8	8.6	1.8

Source: DiMasi (2001:292).

Exhibit 7 Broad Overview of the Research and Development Process

Development of a potential medicine	5000–10000 Active Ingredients	
		Laboratory and animal testing
Pre-clinical tests	250 Active Ingredients	
Approved as test preparation		
Clinical tests	5 Active Ingredients	Phase I—20–100 human test subjects
		Phase II—100–500 human test subjects
		Phase III—1000–5000 human test subjects
Approved as a new medicine		
Marketing		Ongoing tests on the effectiveness, side effects and product safety

and continually modified to achieve the maximum effective treatment with minimal side effects. In this phase up to 10,000 preparations were tested and evaluated. If the preliminary results were promising, then a patent was registered to avoid potential competition for the preparation in advance.

These "New Chemical Entities" (NCE) were subsequently subjected to pre-clinical testing and to a certain extent tested on animals. The objective was to research the toxic effects such as toxicity, carcinogenicity or reproductive effects. In addition, the biological effectiveness of the NCE was strenuously tested.

The preclinical test results were subsequently evaluated by health authorities. If the safety and the effectiveness of the preparation could be ascertained by the previous tests then permission was given for further (clinical) tests. In the US the regulatory agency was the FDA (Food and Drug Administration). This was comparable to agencies in European countries, i.e. at a European level (European Drug Agency). A European patent was only required for some areas and consisted of a bundle of national patents. On average only 5 out of 10000 preparations make it to the clinical tests which were then designated as "Investigational New Drug." The clinical tests were then divided into different phases depending on the country.

If these clinical tests in Phases I to II were positive in terms of human effectiveness and had no side effects, then a new medicine was approved for marketing. However, the pharmaceuticals firms were required, even after market launch, to carry out continuous tests in order to exclude long term or rare side effects. The health agencies could call for additional investigations and tests, change markings and labeling or, possibly, take the medicine off the market even after initial authorization.

The success rate for a new medicine product launch was approximately one out of 5,000–10,000 substances (Exhibit 7). The process also involved considerable costs. In 1975, the average R&D costs for one new drug were estimated at roughly €150 million. By 1987 R&D costs amounted to approximately €344 million. This further increased by 2000 to €870 million (see Exhibit 8). This implied that only around one third of all medicines actually generated revenues that exceeded the research and development costs.

In general, most large pharmaceutical firms had a centralized R&D unit. This hardly changed for several years. Recently the importance of the "new sciences" like biotechnology, genetics, Pharmaco Genomics and Proteomics had increased leading to a growing trend of "personalized medication." The "one drug fits all" policy,

Exhibit 8 R&D Expenses of the Pharmaceuticals Industry in Europe, Japan and the US in Billion EUR at 2006 Exchange Rates

Year	R&D spending
1990	15.9
1995	25.8
2000	48.5
2004	51.6

Source: EFPIA 2006.

which previously characterized large blockbusters, could potentially expire. Medicines for specific patient groups had become more numerous, supported by further developments in the research process. For example there were iterative test processes using imaging methods. These were processes that had little to do with the traditional R&D of the large pharmaceutical firms. Universities and smaller biotechnology firms increasingly ranked higher in innovations than the large pharmaceutical firms. As a result GlaxoSmithKline reacted some years previously and initiated a decentralization process in order to have more flexibility at the research front. It was possible that this trend could continue for the foreseeable future.

In order to provide pharmaceutical firms with an incentive to further invest in the research of new medicines despite high costs, a patent system was developed. Patents were the exclusive right to use an invention. A patent on a medicine gave the patent holder the right to prohibit others to produce, offer or use the medicine commercially. This right was in most countries limited to 20 years. Only in exceptional situations could governments use the right, regardless of the patent, to produce a medicine and make it available to patients without the consent of the patent holder ("compulsory licensing").

Although patents offered a certain protection, the so-called "between-patent" competition posed a dangerous threat to existing pharmaceutical firms. Between-patent competition arose between branded products in the same "Disease Class." Such a therapeutic area comprised drugs that had either the same chemical structure or used the same pharmacological "mode of action" against a disorder. Drugs from the same therapeutic area were, therefore, relatively good substitutes even when the drug was still under patent protection. Most firms researched very similar medicines at the same time. An innovation that led a branded drug and with a new therapeutic area was called a "breakthrough drug" (or first-in-class). New medicines in existing therapeutic areas were "follow-ons." Pfizer's Viagra, for example, was a breakthrough drug when it was launched on the market in 1998. Pfizer profited from a monopoly position and patent protection until 2003 when Bayer introduced a similar product in the same therapy class (Levitra). The times that a breakthrough product existed on the market without any competition were decreasing. First-in-class products which were authorized in the 70s survived on the market for approximately 8 years without follow-on. For products authorized between 1995 and 1998, this time period was only 1.8 years.

In addition the days of excessive high profit margins were over even though "follow-ons" brought only limited therapeutic advantages as governments became more cost-conscious. Even in the US market, which offered 50% profit margins for many pharmaceutical firms, there were signs that the free pricing policy had ended.

The special situation of the market combined with patent laws had caused most firms to earn gigantic revenues with only a few products. Products that generated more than US$1 billion in revenues were called "blockbusters."

Firms tried to make maximum use of the patent protection. New globally standardized products were, therefore, registered for a patent in concerted action worldwide and brought into the market simultaneously (Exhibit 9).

When patent protection ended, generics entered the competition. Often, the generics manufacturers made use

Exhibit 9 Top 10 Blockbusters 2005

Product	Firm	Therapeutic Area	Revenue 2005 in billion USD
Lipitor	Pfizer	Cardiovascular	12.9
Plavix	Sanofi-aventis/BMS	Cardiovascular	5.9
Nexium	AstraZeneca	Gastrointestinal	5.7
Seretide/Advair	GlaxoSmithKline	Respiratory	5.6
Zocor	Merck & Co	Cardiovascular	5.3
Norvasc	Pfizer	Cardiovascular	5.0
Zyprexa	Eli Lilly	Nervous system	4.7
Risperdal	J&J	Nervous system	4.0
Ogastro/Prevacid	Abbott/Takeda	Gastrointestinal	4.0
Effexor	Wyeth	Nervous system	3.8

Source: IMS Health (2006).

of the scientific progress since the development of an old preparation. Consequently, generics could be significantly superior to the originally branded products in effectiveness and side effects. Generics were generally named after the international non-proprietary name of the active ingredient, with the addition of the manufacturer name. Competition for blockbusters was, therefore, extremely high. In the US for example, BMS's diabetes product called Glucophage lost patent protection in 2002. During the previous few years 19 generics competitors entered the market. Market share of the branded product fell rapidly by around 90% in a short span of time.

In contrast to the innovative branded products, generics clearly had a lower profit margin as manufacturers could forego a large part of the expensive development and test phases. These had a positive effect on the cost structure (see Exhibit 10). Therefore, many governments had taken steps to improve the market position of generics to profit from the much lower prices. The share of generics in the total drug market was very different. In the US the number of generics prescriptions exceeded those for branded products for the first time in 2005.

In European countries as well as in Japan, generic drug markets were often still underdeveloped and offered large growth potentials. In the meantime most countries—even outside of Europe—had initiated or implemented measures that gave preference to generics. However, not only the actions of the national health authorities drove the growth of generics' share. Many doctors and patients now had more confidence in generics. The growth of the generics business was estimated at approximately 20% which was higher than the expected growth rate of 5% to −8% on average for the total medicine market.

The competitive pressure for the imminent generics led brand manufacturers to increasingly implement Life Cycle Strategies. The goal was to either increase the time a branded product had on the market without competition from generics; to increase the revenue a product generated under patent protection; or to minimize the loss of revenue to competing generics. Pharmaceutical firms started developing these strategies 6 to 8 years before the expiration of the patent. Around $\frac{1}{3}$ of all medicines, that were in Phase III of the clinical tests in the US, did not contain entirely new chemical entities. This means that they were already sold on the market in a some other form.

A more recent strategy was to bring authorized generic versions on the market. These could be marketed by the original branded drug manufacturer; by the firm's internal generics division or by a generics firm that received an exclusive license for this. In case of licensing, the product was usually produced by the manufacturer to utilize full capacity. Marketing and distribution however was done by the licensee. The producer received, in addition to the licensing fee, a share of the profit. This strategy was particularly useful if generics firms had already contested the patent protection successfully. Instead of costly patent law disputes, this cooperative strategy was a fast and acceptable solution for both sides. When Pfizer's US patent on Zithromax, an oral antibiotic, lost patent protection in 2005, Pfizer's own generics division brought an authorized generic on the market. At the same time, three other firms started with generics for Zithromax. After only seven weeks, the market for the branded drug collapsed and 90% of all prescribed drugs were generics. Nevertheless, Pfizer was able to achieve a 49% market share with its own generic.

Exhibit 10 Costs Per Category in % of Revenues for 2005

Firm	R&D Costs	Cost of Sales
Pfizer	15	17
GSK	14	22
Sanofi-aventis	15	26
Novartis	15	28
J&J	12	28
AstraZeneca	14	22
Merck & Co	17	23
Abbott	8	48
BMS	14	31
Wyeth	15	29
Eli Lilly	21	24
Teva[1)]	7	53
Sandoz[1)]	9	61
IVAX[1)]	6	58

Source: Company annual report.
1) Teva, Sandoz and Ivax are primarily generics manufacturers.

The Supply Chain

From manufacturing to consumption by the patient, a medicine went through a number of steps.

Production

Fine chemicals were the production base for most medicines. Branded products made up between ten to fifteen percent of the medicine price. Generic products comprised about 25% to 30% of the medicine price. Half of this global medicine market was manufactured by the pharmaceutical firms themselves; whereas the other half was produced by firms from the fine chemicals industry. These fine chemicals consisted of standard practice or customized molecules

and active agents that were prepared for further processing into the final medicine in pill, fluid or gaseous form. The fine chemicals could be seen as mass-production items or raw materials that could normally be produced by various firms in high quality. As a result, there were many potential suppliers. No chemical firm had been able to achieve a dominant market position and the market to date remains highly fragmented. The pharmaceuticals industry was by far the largest buyer of fine chemicals and a substantial percentage of chemical firms' revenues often depended on a few pharmaceutical customers. Medicine manufacturers, on their part, must guarantee high product quality. To produce a specific medicine, every factory needed exactly defined processes and a permission that was checked regularly. If health institutions assessed that there were variations in the areas of quality, safety and effectiveness, then product authorization could be withdrawn immediately.

Distribution and Pricing

Wholesalers and pharmacies ensured that the products reach the patients. In this area, there were large differences between the US and the European markets. In most European markets maximum mark ups for pharmacies and wholesalers were set by the health authorities. In the US, there was considerably more flexibility. On average, the medicine manufacturer received around 60% of the sales price, the wholesaler around 7% and the pharmacy about 20%. (See Exhibit 11.) The wholesalers bought directly from the drug manufacturers and distributed the product further to hospitals and pharmacies. To carry out his function, the wholesalers needed a license and were required to conform to certain criteria, e.g. keep a safety stock, so that they could deliver within a short time. Moreover, they often had to cover a whole region—and guarantee the integrity of the drug.

Around 94% of the medicine provided in the EU was undertaken by wholesalers. Nevertheless, a multichannel system dominated Europe, in which a product could be sold by multiple wholesalers. Large pharmacy chains, specialized pharmacies and mail order pharmacies could to some extent buy the medicines directly from the (medicine) manufacturer as well. The growing importance of chains and mail order houses in Europe led to an increasing trend to bypass the distributor. Hence, in February 2005, Pfizer announced that it would deliver directly to pharmacies, to fight parallel imports.

Price pressure on the wholesalers had risen over the previous years resulting in tighter competition. The net profit margins were decreasing and averaged around 0.7 to 0.8% of sales price. A reason for this was increasing packaging, delivery, and transportation costs that could be attributed to the rising oil and fuel prices. Another reason was the trend of medicine manufacturers to establish Just-In-Time production systems which limited the wholesalers' opportunities to profit from efficient ware-house management. As a result, the industry both in the US and Europe had undergone substantial consolidation over the last decades. In the EU-15 countries, the number of wholesalers declined from 600 in 1990 to around 150 in 2004. In US market the three largest wholesalers control approximately 90% of the market.

Pricing was more critical for generic manufacturers because they are traded in larger mass volumes. In particular, the competitive environment in generics for each of the respective therapeutic areas played a major role. In addition, the ability of the wholesaler to support the manufacturer in

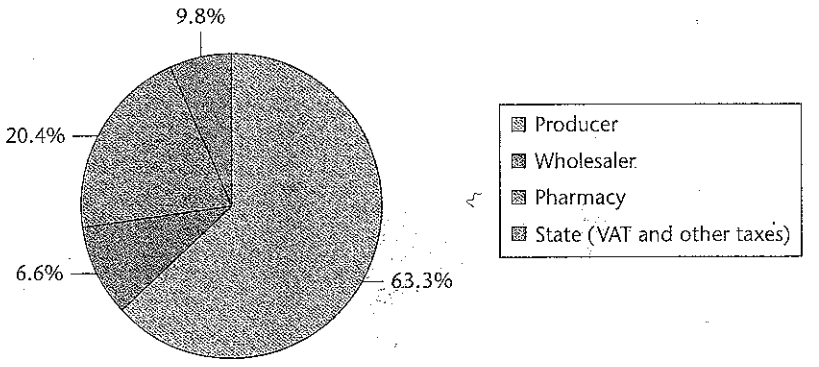

Exhibit 11 Composition of sales price

Source: EFPIA 2006.

revenue or volume growth as well as the prevention of parallel imports further affected the price levels for generic drugs. Many distributors had added activities to their core business, for example, services in the areas of market data gathering and processing or packaging. For the manufacturers, distributors increasingly offered marketing and advertising support activities as well as support in the area of logistics, which was necessary in the clinical tests, or in product launches. Some distributors had even vertically integrated, both downstream and upstream, and had taken over production and pharmacy functions. This strategy, however, was disliked by national health authorities and was highly restricted.

The significance of pharmacies varied from country to country. Prescription drugs were generally only available through pharmacies. But the influence of pharmacists on the choice of drug or the brand was dependent on the respective legal environment. Principally, the decision on which medicine was consumed by patients was made by the prescribing doctor. In many countries, however, the pharmacist was allowed to replace the original prescribed branded product with a preparation that contained the same active agents. Pharmacies usually bought medicines directly from wholesalers and even this was strongly regulated in all countries. In most European countries, for example, only pharmacists could operate pharmacies. The number of pharmacies that could be owned by a single owner was limited. A license was required. Over the last years, however, there had been tendencies to lighten this regulation.

Competition among Pharmaceutical Firms

In comparison to other industries, the pharmaceuticals industry was highly fragmented. Over the previous few years there has been a tendency for firms to consolidate. In 1988 the top ten pharmaceutical firms had a market share of around 25%; whereas, in 1996 the same group held around 33% of the market. As more mergers and consolidations occurred, it was reported that by 2006 the market share of the top pharmaceutical firms improved to 43.3%.

All top ten firms were research-oriented companies (Exhibit 12). Only Sanofi-aventis and Novartis included a large generics domain into their activities. Others were also active in the OTC market, diagnostics, and in non-medical consumer goods. Overall, most firms were highly vertically integrated compared to other industries and carried out R&D, production, marketing and distribution activities. Some experts, therefore, claimed that these firms should focus more on their specific core competences, such as R&D or marketing & sales, make use of contract research and independent development firms as well as incorporating freelance marketing organizations into their business.

Pfizer was the undisputed market leader. Its core business consisted of 86% prescription drugs for humans. The division "Consumer Health Care" which included personal hygiene and OTC-products (approximately 8% of total revenues or US$4 billion) was sold to Johnson & Johnson in June 2006 for US$16.6 billion. Four percent of

Exhibit 12 Top 10 Pharmaceutical Firms 2006

Company	Origin	2006 Revenue (in billion US$)	Growth 2005–2006 (in %)	Average Annual Growth 2001–2005
Pfizer	USA	46.1	−0.7	4.8
GlaxoSmithKline	UK	37.0	5.5	5.0
Sanofi-aventis	France	31.1	1.4	11.2
Novartis	Switzerland	31.6	6.1	14.1
Johnson & Johnson	USA	27.3	1.2	9.2
AstraZeneca	UK	26.7	11.2	7.0
Merck & Co	USA	25.0	4.9	4.1
Roche	Switzerland	23.5	16.1	13.5
Abbott	USA	17.6	6.4	10.7
Amgen	USA	16.1	20.6	30.2
Total Top 10		282.1	5.7	8.8

Source: IMS Health 2006.

Exhibit 13 Size and Development of R&D Spending for Selected Industries

Industry	R&D spending in % of revenue 2004
Pharmaceutical industry and Biotechnology	15.3
Software and Computer Services	10.7
IT Hardware	8.6
Automotive	4.3
Electronics and Electrical Equipment	5.6
Chemicals Industry	3.7
Food Industry	1.8
Telecommunication	1.5
Average of all industries	3.8

Source: EFPIA 2006.

Exhibit 14 Number of Developed New Molecular Entities (NMEs) and Biotechnology Products Between 1997 and 2004

Year	Number of new NMEs
1990	36
1991	51
1992	43
1993	40
1994	40
1995	41
1996	36
1997	46
1998	37
1999	41
2000	32
2001	31
2002	28
2003	26
2004	25

Source: EFPIA 2006.

Pfizer's revenue was generated by the division "Animal Health Business." Pfizer was most active in the cardiovascular diseases and metabolism diseases therapeutic areas. Close to half of the company's total revenues were generated from prescription drugs. In the meantime, Pfizer had divested its generics business which had been previously integrated into the company after the acquisition of Pharmacia in 2004. Instead, it had bought some smaller biotechnology firms. The patents for its second and third best blockbusters, namely, Zoloft and Norvasc expired at end of 2006 and 2007 respectively.

GlaxoSmithKline (GSK) was somewhat more differentiated. The pharmaceuticals division was responsible for 86% of the revenues. The remaining 14% was contributed by the consumer goods and OTC division. Therapeutic focus concentrated on respiratory diseases (27% of revenue), nervous system diseases (17.2%) and antiviral drugs (13.9%). GSK is currently expanding in the vaccine business (7.4% of revenues in 2005) and is broadening its biotechnology base by acquiring several smaller firms. For two of the top five products, new generics had recently appeared on the market. In the OTC market, GSK was presently number 3 worldwide.

Sanofi-aventis was a firm that emerged from the merger between Sanofi-Synthélabo. This was the result of earlier multi-mergers between Hoechst and Rhône-Poulenc and Aventis. Sanofi-aventis was dominated by its pharmaceuticals division (92% of revenues). The remainder was generated by the vaccine business. The firm was active in seven different therapeutic areas. The pharmaceuticals division included a generics department, which covered only 14 European countries. In March 2006, around 25% of the Czech generics manufacturer Zentive, a leading firm in Central-Eastern Europe, was bought. Together with Merck & Co., Sanofi-aventis operated a Joint-Venture in Europe in the OTC and the vaccine products.

Novartis' business was divided into three main segments, namely: Branded products (innovative prescription drugs that contributed 63% of revenues in 2005) and generics, which represented 15% of the revenues and were marketed under the name Sandoz. Both were grouped together in the pharmaceuticals division. The third branch was the Consumer Health Care division that consisted of the OTC business, animal products, baby food, food supplements and contact lenses. During the previous years Novartis expanded primarily through acquisitions such as Sandoz (the Slovak manufacturer LEK in 2002), the generics business of AstraZeneca (2004), the German firm Hexal (2005), Eon Labs (2005) and Chiron (2006) for the vaccine and diagnostic branches. The Consumer Health Care division was also restructured by the purchase of the foods business as well as the Consumer Health division of Bristol-Myers Squibb (2004). At the same time, however, the dietary products division and further food divisions were sold off.

Johnson & Johnson (J&J) was a highly differentiated conglomerate and was highly decentralized. The pharmaceuticals division contributed only around 44% of the revenues. About 18% of total revenues were generated by the Consumer division which encompassed the OTC products, food products and supplements, skin care, and children's products. Within the pharmaceutical division, the therapy focus was on nervous system disorders, anti-inflammatory drugs and hormone treatments. J&J had bought firms for

Exhibit 15 Share of the Top 5 Products in the Total Revenue in Percent

Firm	Product 1	Product 2	Product 3	Product 4	Product 5
Eli Lilly	29	9	8	7	7
Wyeth	18	9	8	6	5
BMS	20	12	5	5	4
Roche	12	6	6	5	5
Merck & Co	20	14	14	14	3
AstraZeneca	19	12	7	7	5
J&J	7	7	5	3	3
Novartis	11	7	4	4	3
Sanofi-aventis	8	7	6	6	6
GSK	14	3	3	3	3
Pfizer	24	9	6	3	3

Source: Company annual reports 2005.

all its business areas over the last years. In the OTC market, J&J was the global market leader.

AstraZeneca operated only one division: pharmaceuticals. The five main therapeutic areas were gastrointestinal diseases (27% of total revenues), cardiovascular (23%), neuroscience (17%), oncology (16.5%) and respiratory diseases (12%). In the beginning of 2006 AstraZeneca acquired the biotech firm KuDOS.

The US firm **Merck & Co** had long been considered as the largest pharmaceuticals firm globally. The firm still suffered the consequences of the premature market withdrawal of the arthritis product Vioxx in 2004. Vioxx was launched in 1999. Merck sold over US$2.5 billion worth of this arthritis drug in 2003 alone. Ongoing tests, however, showed a heightened risk of a heart attack for Vioxx, which led to the immediate withdrawal of the license. Because of this, Merck became a takeover target on the stock market with its stock price dropping almost 30% on the day of the announcement. By 2008, two more important products would lose patent protection. Merck operated almost exclusively in the area of prescription drugs (95% of revenues). Merck was the only top ten firm that had not been involved in the large horizontal merger over the last 15 years. In 2004, Merck sold its 50% stake in a European Joint-Venture of non-prescription pharmaceuticals to its partner J&J.

Roche's pharmaceuticals division contributed 77% to total revenues. The most important division for the company was the diagnostics area. However, a large part of the sales (about 1/3) originated from the consolidated majority stake in the US biotech firm Ganentech and the Japanese firm Chugai. Roche was the market leader in oncology with 40% of revenues based on anti-cancer medicines. 15% of total revenue was contributed by virology and 8% by transplant pharmaceuticals. In 2004 Roche sold off the Consumer Health division to Bayer. Acquisitions were made in the area of biotechnology. Novartis owned one third stake in Roche.

The US firm **Abbott** realized 61% of its revenues from the pharmaceuticals division. The remaining revenues were contributed by the diagnostics and the food products. Abbott owned 50% of TAP pharmaceuticals, a Joint-Venture with the Japanese firm Takea. During the last years Abbott made some acquisitions, mainly to strengthen the area of medical devices (stents) and diagnostics.

Bristol-Myers Squibb (BMS): almost 80% of the total revenues was generated by the pharmaceuticals division. BMS had a strong presence in the field of cardiology, virology and oncology. In the future BMS wanted to specialize even further in "Specialty Products." In 2004, the adult nutritional division was sold to Novartis. In addition the Consumer Medicines Business was divested in 2005. The expiry of the patent for a blockbuster Pravachol in 2006 combined with the difficult market conditions resulted in weaker financial results for BMS. Another burden for the company was the lost patent law suit against a Canadian generics firm for the blockbuster drug Plavix.

Pfizer's Future Strategy

Kindler announced a radical change in strategy that would encompass multiple divisions and Pfizer's corporate culture: He was quoted in an article as commenting: "There are no longer sacred cows."[4] This was very uncommon for the hitherto profitable industry.

In January 2007, he announced that 10,000 employees would be dismissed. This was around 1/10 of Pfizer's total

employees. One fifth of the sales force in the US and in Europe had to go. Five research centers and several factories were closed down. Research was reorganized. Instead of globally dispersed "Centers of Excellence," research activities were structured around five therapeutic areas (e.g. Cancer, Diabetes). In the future Pfizer had to minimize losses in research and development costs resulting from the delayed identification of potential long lasting side effects such as in the case of Torcetrapib. To achieve this, Kindler wanted to integrate General Electric's "fast falling" policy. In addition, Kindler aimed to encourage his "traditionally isolated" researchers to do more external collaboration. He had already ordered that Pfizer's research initiatives (often referred to as the "pipeline") be broadcasted via the internet to provide the public and competitors with relevant information to foster focused collaboration or acquisitions. Finally, Kindler demanded a paradigm shift regarding the product portfolio: "We need to be as effective at selling a large number of US$500 million drugs as we are at selling drugs with multi-billion dollar sales."[5]

Would all this help Pfizer? Would collaborative research and streamlining Pfizer's existing operations prove effective? The stock market appeared to be skeptical. In contrast to normal financial market reactions to similar corporate announcements, Pfizer's stock price fell after the announcement of employee cuts.

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Endnotes

1. Quoted directly from the article "Billion Dollar Pills" in *The Economist*, January 27, 2007.
2. Ibid.
3. Note to reader: The OTC market will not be further discussed within the parameters of this case study. The focus of this case is primarily on prescription drugs.
4. Quoted directly from the article "Billion Dollar Pills" in *The Economist*, January 27, 2007.
5. Ibid.