

Economics 333

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Prescription Drug Market

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Prologue

Patent laws were developed during the Industrial Revolution to protect the inventions from being copied until the inventor had had a chance to recover the costs of the research and development used to create the product. Patent laws are now the greatest tools a pharmaceutical company has ever had.

There are, however, several areas of interest that arise from the pharmaceutical industry and how patents are used. Patent laws prevent anyone but the owner of the patent to manufacture the product in question, the after effects of this is the creation of monopolies, or at least companies with huge market power where one particular drug is involved, and increased barriers to entry for the pharmaceutical industry. In order to encourage R&D, the government has begun to subsidize the cost of the process. This leaves the pharmaceutical company with little expense of their own which is contrary to the whole purpose of patents. As patents became more widely used, so did the concealment of drug R&D, testing, and submission for approval which creates more than a few headaches at the broker's office. Also rising from the pharmaceutical industry is a new industry that manufactures generic drugs. Semi-duplicates of the brand name drugs at a lower price to give big time brands a run for their money. All four aspects of the market important and are discussed in further detail within the following pages.

Generic Drug Market

Generics have always been in existence along with branded pharmaceuticals. However, the industry was restricted to a few small players. One of the major events that are acknowledged to be the start of the modern generic pharmaceutical industry was the approval of the Drug Price Competition and Patent Restoration Act in 1984. This law, often called the "Waxman-Hatch Act," which permitted manufacturers to file ANDA's (Abbreviated new drug applications) for generic versions of all post-1962 approved pharmaceutical products.

This act opened up the possibilities for generic competition for pharmaceutical products, by creating what is now the modern pharmaceutical industry. In the first year following approval of the Act, more than 1,000 applications for new generic drugs were received by the FDA. The subsequent growth of the generic pharmaceutical industry, from \$2.6 billion dollars in 1990 to nearly \$10 billion in 1998 was fueled by the market exclusivity for a large number of products, making them available for generic competition.

The potential for companies to earn millions if first to the market with generic products, resulted in a crisis that virtually destroyed the generic industry four years after the passage of the Waxman-Hatch Act. The rush to launch generic versions of branded pharmaceuticals created intense pressures on the FDA to approve products, and on manufacturers seeking to be first to market. In the late 1980's some manufacturers falsified applications, going so far as to alter branded pharmaceuticals and submit them as their own. This scandal slowed the new product approvals for all generic companies, with the FDA approving approximately 80 abbreviated new drug applications in 1990, as

compared to more than 250 in 1989. As an outgrowth of the scandal, the demand for heightened scrutiny of all aspects resulted in FDA inspections of manufacturers and testing firms, and the analysis of more than 2,800 samples of widely used generics.

Over the past decade, generic drugs have more than doubled their share of the prescription market - from 18.6 percent at the end of 1984 to 36.5 percent in 1998. The large number of innovator products due to lose patent protection over the next 10 years will foster growth in the generics industry.

The major reason for the future growth of generic drugs is of course the costs. The costs of producing generic drugs are generally 40 percent to 60 percent less than the production of brand name drugs. This is due to the extremely high costs of research that are associated with the development of brand name drugs. The research costs usually range from \$400 million to \$500 million, and these costs trickle down to the consumer. Generic drug manufacturers do not have these costs. The research has already been done by other makers.

One of the most significant reasons that may slow the growth of generic drugs is the use of patent laws. These patents generally last for about 20 years, and keep generic drug makers from getting the ingredients used for their pharmaceuticals. After the 20-year period is over the ingredients are fair game. Major drug manufacturers are using this to keep prices high and keep other drug makers out of the industry.

Stock Market Concerns

Pharmaceutical companies have, classically, done everything in their power to protect their own interests and maximize their profits. Through research and development, companies create new drugs to combat nearly everything that ails the human race. In the early years of this market, it was not at all uncommon for companies to rip off the ingenuity of the R&D of other companies in order to make a buck off it for them. To keep up with the competition, as it were. After patent laws were made easier for pharmaceutical companies to attain and the government took more responsibility for enforcing their patents, development and creativity began to run wild. These improvements really only delay this rush to attain the recipe for a drug and put it out on the market until after the patent runs out. A recent example of this is the expiration of the patent for Prozac. The expiration of this patent cost Eli Lilly & Co. because Prozac was Lilly's best selling drug¹.

Investing in pharmaceutical companies also came to be considered a wise and potentially profitable investment. Even so, pharmaceutical investors do tend to be extremely sensitive to a company's drug testing and approval. When ImClone met with the FDA to discuss the approval of their new cancer drug, ImClone stock rose \$5.01². ImClone then said that the drug wasn't approved but that the company was going to start a new set of trials for the drug for a second chance of getting the drug approved. Again the stock price rose³. Because even the slightest change in perceived test and approval results would cause a substantial push or pull of company stock, usually investors trying to get rid of their stock, the pharmaceutical companies began to take great measures to

¹ Shook, David. How Lilly Could Bloom Again.

² Dillon, Nancy. ImClone Stock Soars After FDA Meeting.

conceal the progress of drug testing. This was to attempt to stabilize the company's finances, considering that having most large investors pull out while testing isn't going too well doesn't help the company at all.

There are a few consequences of this increased secrecy. Firstly, potential investors tend to be more cautious of investing large amounts in pharmaceutical companies because if testing and approval aren't going well, investors won't know until the stock has already dropped in price. Sometimes greatly dropped in price. An example of this is the recent \$18.74 drop in the stock of OSI Pharmaceuticals after reporting "disappointing" results of the trials of a new cancer drug the company had been working on^{4,5,6}.

There is also the now infamous scandal concerning ImClone and its failure to get approval for a cancer drug of its own^{7,8}. This leads to the next consequence of increased secrecy concerning drug testing, insider trading. Insider trading is a felony that results from an investor acting upon information that hadn't yet been released to the public. Concerning the ImClone example, Martha Stewart has been accused of insider trading because she sold her ImClone stock the day before the company announced its failure to get its drug approved⁹.

Recently, there has also been a rash of stock analysts posing as students, doctors, teachers, etc. and trying to obtain inside information about the development of a drug to help their clients in making a more enlightened decision regarding whether to keep, buy,

³ Pollack, Andrew. Market Place; Cancer Drug From ImClone May Receive New Review.

⁴ Rough day for Drug Stocks. Wall Street Journal.

⁵ Ball, Deborah and Naik, Gautam. AstraZeneca Cancer-Drug Trial Yields Disappointing Results. Wall Street Journal.

⁶ Herper, Matthew. AstraZeneca Cancer Drug Hits Major Setback.

⁷ Unknown. ImClone's Double Dose of Bad News.

⁸ Pollack, Andrew. ImClone Hunts for Records of Those Treated with Drugs.

or sell a pharmaceutical companies stock¹⁰. Needless to say that while patents and private testing are great tools for pharmaceutical companies, it does create some new and unnerving problems that companies must deal with. Not to mention the stock broker with their growing ulcers losing sleep and appetites wondering about pharmaceutical drug testing and development and the investors running the risk of losing more than their shirts while being left totally in the dark about their financial futures.

⁹ Patsuris, Penelope. Martha: In a Class By Herself.

¹⁰ Anand, Geeta and Smith, Randall. Analyst is Focus of Investigation Over Drug Data. Wall Street Journal.

Subsidies for R&D

The pharmaceutical market is unique due to the public need for these private goods. If drug companies were to simply settle for selling blockbusters such as Tylenol, Viagra, and allergy medication they would still be highly profitable. There are numerous niche drugs which make very little or no money. For many, these drugs are far more important than the blockbusters.

Therefore, the government, through public labs and state universities, spends incredible amounts of money subsidizing research and development in order to increase invention and innovation in the niche markets. Much of the early basic research that may lead to drug development is funded by the National Institutes of Health¹¹. It is usually only later, when the research shows practical promise, that the drug companies become involved.

The effect of government subsidies has not been a one for one increase in the amount spent on subsidies. Drug companies spend a strikingly small amount on research and development. The top 10 drug companies are reported to spend on average about 20 percent of their revenues on research and development¹². At surface, this percent is surprisingly low when considering the nature of the market. The magnitude is more remarkable upon comparing it to their other costs. According to its annual report, Pfizer spent 39.2 percent of its revenues on marketing and administration in 1999¹³; Pharmacia & Upjohn is reported to have spent about the same¹⁴. Marketing costs are twice those of research and development, the lifeblood of a market based on innovation.

¹¹ Gerth J, Stromberg SG. Drug makers reap profits on tax-backed research.

¹² Tanouye E. Drug dependency: U.S. has developed an expensive habit: now, how to pay for it?

¹³ Annual report, 1999. New York: Pfizer.

¹⁴ Gerth J, Stromberg SG. Drug makers reap profits on tax-backed research.

Along with subsidies, drug companies enjoy incredible tax breaks. Not only are its research and development costs deductible, but so are its massive marketing expenses. The average tax rate of major U.S. industries from 1993 to 1996 was 27.3 percent of revenues. During the same period the pharmaceutical industry was reportedly taxed at a rate of only 16.2 percent¹⁵. With tax breaks, the drug industry is culpable for almost none of its research and development. Pharmaceutical companies are no longer culpable for creating and researching drugs, but are now machines designed to market and sell the drugs.

Consequently, drug companies are unsettlingly profitable. The top 10 drug companies are reported to have profits averaging about 30 percent of revenues -- a stunning margin^{16,17}. Not only are their costs incredibly low, their revenues remain high. Over the past few years, the pharmaceutical industry as a whole has been by far the most profitable industry in the United States^{18,19}. According to Fortune Magazine, in 1999 the pharmaceutical industry realized on average an 18.6 percent return on revenues. Commercial banking was second, at 15.8 percent, and other industries ranged from 0.5 to 12.1 percent²⁰. It is amazing that a seemingly altruistic cause can create the most profitable industry.

This has accumulated in a large increase in the prices of drugs. According to Families USA, an organization favoring a drug benefit, the average annual cost of prescriptions for seniors more than doubled between 1992 and 2000, from \$558 to

¹⁵ Anderson C. Drug firms said to pay less in taxes.

¹⁶ Bernstein S. Drug makers evolving marketplace.

¹⁷ Unknown. The pharmaceutical industry.

¹⁸ Tanouye E. Drug dependency: U.S. has developed an expensive habit: now, how to pay for it?

¹⁹ Unknown. How the industries stack up.

²⁰ Unknown. How the industries stack up.

\$1,211. The government is responding by passing legislation to change subsidy levels. However, they are solving the symptoms and not the problem. The House approved legislation to help senior citizens meet the costs of prescription drugs. The bill does nothing to affect the costs or prices of prescription drugs. Instead, it gives a discount to consumers. The bill was passed, on a 221-208 vote. If it were to become law, the bill would mark the biggest expansion of federal health subsidies for senior citizens since Medicare was created in 1965²¹. This does not insure decreases in price levels, but instead shifts the burden of prescription drugs costs from the elderly to tax payers.

²¹ Los Angeles Times. July 28, 2002

Monopolies

It is no surprise to American citizens that pharmaceutical companies own some of the largest monopolies in the U.S. economy. Who is going to regulate these medical monopolies? The U.S. government gets their cut through taxes. So, it seems that the government is not in a hurry to regulate the rise in prices. Drug monopolies are on one side, raising the cost of medicines each year by almost twenty percent. On the other side the big corporations are angry about having to make big payments for prescription drugs for their retired workers. Is it the big corporations that are suffering in this fight? Who is really suffering?

The average hard working employees are the people who suffer from these pharmaceutical monopolies. Big companies will dump the rapidly growing costs of medication on the retired workers. There is no reason why people, who have worked hard their whole life, should have to pay for these unregulated price increases. The pharmaceutical companies of the United States have increased the price of individual drugs by 50% since last year. They have also encouraged the use of costlier drugs and encouraged an increase in prescriptions. What can the average Joe do in this situation? The answer seems to be unfortunate. Nobody can put a price on the health and well being of our loved ones.

Lawyers for the pharmaceutical monopolies apologize for the high prices, but claim that it is used to fund research in order to improve medicinal quality. In lieu of such sporadic price increases, it would seem that the monopolies give priority to profits instead of customers. When a pharmaceutical company succeeds in obtaining a patent on a new drug, they are able to charge monopoly prices as long as the patent lasts. If this

were the case, then why would the pharmacies want to allow new drugs (whether or not they can improve the remedy of certain illnesses) or new manufacturers into the market? In a sense, they would be losing money along with our government.

The fact that the monopolies would not want other alternatives or new drugs to help patients (whether proven efficient or not) is most apparent in the case of drugs for treating AIDS. Herbal remedies can be used to treat many symptoms of the deadly AIDS virus at a lower cost. For example, some states already practice the use of marijuana to stimulate the appetite of AIDS victims, also to treat leukemia patients in chemotherapy, etc. Why is it that there is not more prescriptions or over-the-counter herbal supplements? Maybe this is the reason why most eastern medicines are not widely accepted in many western countries (especially the United States).

Monopolies have revealed themselves too much with drugs for treating AIDS patients. Other companies could provide these drugs for 70% less than patent holders Merck and Co., Bristol-Meyers Squibb, Glaxo-Wellcome, and still make profits! For example, there is a blatant corruption of the AIDS drugs dilemma in South Africa. Pharmaceutical monopolies initiated a lawsuit against the South African government for refusing to drop drug prices for the millions of people on the African continent infected with HIV/AIDS. Eventually the monopolies realized the error of their ways and that they were basically trying to (in so many words) turn their backs on millions of dying people. The lawyers of the pharmaceutical monopolies not only surrendered, but also agreed to pay court costs of the defendant (the South African Government).

Epilogue

Without a doubt the pharmaceutical market is a tangled web of complex laws and tight-lipped executives working hard to create a drug that will make them millions. But more than that, the pharmaceutical industry is one that simply can not be avoided in our society. It is for this reason that this market remains structures as it is and almost totally hidden from the public's eye. In future papers, specific examples of the market structure will be discussed in from the perspectives of the areas discussed in this paper. But for now, Fin.

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