Pharmacoeconomics: The Economic Effects of Brand-Name Loss of Exclusivity and Generic Entry

Khalid Yasseen, Irvine Valley College
Mentor: Mark Collinson

Abstract

The $790bn pharmaceutical industry develops, manufactures, markets and distributes drugs and medications. Many sectors specialize within the industry across disease states and markets with drugs enjoying lesser or greater barriers to entry from competition. If a manufacturer has a patented drug within a class, it has a monopoly.

During the protected period, the monopolist absorbs consumer surplus, generating supernormal profits in hopes that they exceed the total amount spent by the research and development of the drug and provide an additional surplus that will allow future innovation. Drug markets undergo significant changes to their competitive dynamics when patents expire, at which time the prescription-branded medication competes with new generic versions of the original.

Post patent expiry, new firms can replicate the patented drug and enter a sector while enjoying low marginal costs and economies of scale. Thus prescription-branded and generic manufacturers can still over-charge and under produce medications compared to a market with fewer barriers. An economic analysis of the industry market structure reveals that firms participate in oligopolistic competition whereby the legally-protected product competes with the newly arrived relatively undifferentiated products.

Furthermore, there is some complexity to that market structure: Generic medications tend to be more consumer-friendly than prescription-branded medications. Yet the undifferentiated generic versions of the drug may compete more with themselves, each facing a more elastic demand, than with the unprotected branded version. Analyzing the economic effects of the industry will help patients make informed decisions.

Patent Expiration

After the drug patent has expired, there is no longer legal protection of the drug allowing generic manufacturers to produce and sell that drug. The generic drug manufacturers have lower average variable costs since research and development and marketing costs are not needed. Lower average variable costs drive drug price down, passing on savings to the consumers. Once approved by insurance companies, generic alternatives become the most demanded, and the brand-name drug loses most of its supernormal profit.

Government regulations are much more stringent on newly entering drugs then on generic drugs. In order to be able to produce and sell drugs, generic manufacturers must prove their compound is bioequivalent to the brand-name medication. In many cases, the brand-name manufacturer can apply to develop the generic medication, though this is usually rare.

In December 2017, Pfizer entered the generic market for the widely known and used medication Viagra® after its patent expired in December. Pfizer's decision to produce the generic was its attempt to continue selling and absorbing supernormal profits of its market hit drug. At $65—pill for 20 years, Pfizer enjoyed large revenue, with 1.5 billion in 2016 alone. Once generic however, Pfizer was at risk of losing profit on this drug. Entering generic manufacturing for sildenafil (Viagra®) will allow Pfizer to continue earning profit since many generic manufacturers still need to get approval for production.

Due to the lower cost of the generic bioequivalent, annual sales of the brand-name decreases significantly after each passing year. This is because the brand-name manufacturer faces two choices when patent expiry occurs: competitively price the brand-name or leave the price the same and face an elastic demand. Most pharmaceutical companies tend to leave the brand-name drug price the same, since they will still receive some revenue from the product. Ultimately, the pharmaceutical company realizes that it's best profit-seeking decision would be to cut its losses and invest in the research and development of a new drug.

Market Structure

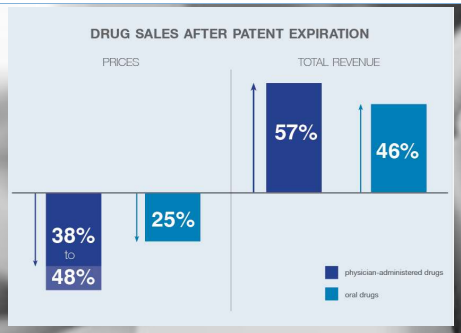
Pharmaceutical companies are unique in their market structure due to the fact that the user of the product is not necessarily the payer. The patient, the primary beneficiary of the medication, pays a copay and/or premium to a third-party payer, an insurance company.

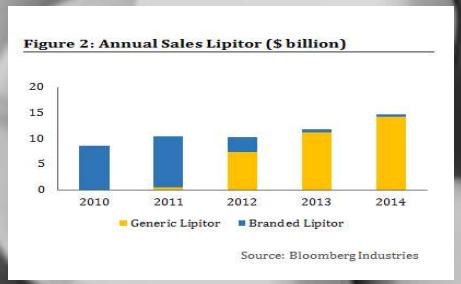
The pharmaceutical industry receives its revenue from the insurance company, and thus is able to charge high prices. The insurance company, in turn, demands copays, premiums, and deductibles from the patient and is able to price-discriminate.

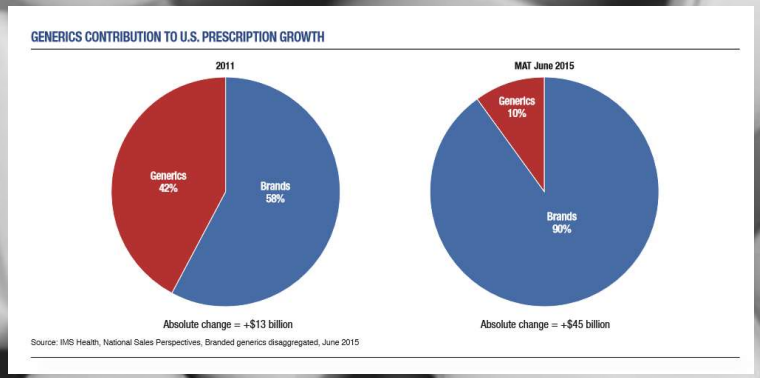
Brand-name pharmaceutical manufacturers are best described as monopolies due to the barrier to entry they enjoy. Patents on drugs inhibit competitors from manufacturing and selling the same medication, allowing pharmaceutical companies to obtain supernormal profits throughout the length of the patent. In addition, the company has large economies of scale that allows it to drive its average costs down below that of any start-up pharmaceutical company.

However, the monopolist still faces competition from other pharmaceutical companies attempting to break that barrier by developing a different drug with the same physiological effect. In this way, the pharmaceutical company acquires some oligopolistic behaviors due to competition from few other pharmaceutical companies. Many pharmaceutical companies specialize in specific drug markets, and thus compete with only a few other brand-name manufacturers.

The generic drug market is best described as an oligopoly, consisting of a few manufacturers of any one drug and all pricing relatively the same. A defining characteristic of oligopolies is the practice of collusion, which came into the public eye in 2016 when the Department of Justice was looking to file collusion charges against top generic manufacturers. Of these included Mylan, Teva, Lannett, Impax and Endo. An example of this collusion came with the drug Ursodiol, which is sold generic by 8 companies, being priced at $0.45/capsule. In 2014, Lannett raised the price to $5.10, and each competitor began pricing at a similar price.







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