

The War on Generic Drugs

DECEMBER 1, 2020

By Chris Toavs

The intention of the patent was to encourage innovation by promising absolute intellectual rights. Patents hold a crucial role in the pharmaceutical world they prevent market failure and allow for extensive investment in research. However, patent-protected drugs face no price cap or competitors for a minimum of twenty years, guaranteeing patent holders market exclusivity (Gabriel, 2014). As a result, consumers currently pay enormous amounts of money to obtain their medications, leaving them with no other options to access drugs. Unreachable prices push people into a survival mindset. Rationing supplies and alternative solution drugs are a few of the harms consumers face. Despite their initially positive goal of protecting intellectual property rights, patents, in the hands of pharmaceutical companies, actually create profitable pharma monopolies that also prevent patients from accessing vital medications. To reprioritize patient access to necessary medicine over corporate profit margins, generic drugs ought to be more readily available and less restricted by patents.

Pharmaceutical companies in the United States have long had a vexed relationship with patents, which they avoided or used only as the patents served the corporation's financial interest. Due to the antebellum market and increases in meeting public demands, "[b]y the 1840s[,] the drug trade in the United States had become a diverse and complex enterprise" (Gabriel, 2014). Drug manufacturers frequently turned down patents for fear of exposing harmful ingredients in their medicine. Drug ingredients were trade secrets because companies did not desire to disclose controversial, and perhaps illegal, ingredients. Before the antebellum era, patents were used for commercial purposes. Near the end of this era, patents presented an opportunity for economic growth. Pharmaceutical monopolies favored the use of patents for empire expansion. Orthodox physicians recognized the corruption festering between pharma companies and patents and worked "to suppress the use of patent medicines" (Gabriel, 2014, p. 43). Patents are weapons. Pharma monopolies now use patent manipulation in a modern-day race to arm themselves for a single sided war. If old patents are retained and new patents are obtained, then pharma monopolies profit.

While patents fill pharmaceutical monopolies' arsenals, restricting medication manufacturing harms consumers. A patent guarantees a market with no competitors. Pharma monopolies virtually control all variables of the market because the monopolies allow the companies to fix prices on drugs that chronically ill customers need. With no obstacles these monopolies generate a huge amount of money by robbing dependent consumers. Average middle-class people cannot afford to purchase medications. Valeant Pharmaceutical Company is a prime example of such patent abuse. While patents originally aim to incentivize research and development by protecting innovative findings, Michael Pearson, the CEO of Valeant, claims that his company will ignore research and focus only on the distribution of drugs. Rather than generate profit through innovation by developing new drugs, Pearson simply buys rival drug companies and uses those companies' old drug patents to create a drug giant built upon "price gouging, a secret network of specialty pharmacies, and fraud" (Gandel, 2015). As the Valeant example reveals, patents help CEOs and companies line their pockets while keeping drugs from people who need them.

As the Valeant example suggests, patents drive up the price of the drug for the consumer by halting the manufacturing of reasonably priced generic drugs. Generics are the same chemical compound as brand name drugs; however, they cost substantially less. Patents grant absolute power and eliminate hope for generics because no company will willingly surrender the opportunity to make money. Preventing the sale of generic drugs creates a vicious cycle consumers have no choice but participate in. Prices on brand-name drugs continue to increase, and consumers and healthcare providers must pay. Ironically, drugs for non-life-threatening conditions escape this cycle because generic brands exist for common over-the-counter drugs such as analgesics, antibiotics, and vitamins. Diphenhydramine HCl, for instance, is the counterpart generic to the brand Benadryl. However, there exists almost no generic option for life-saving medicines like insulin, HIV drugs, and spironolactone, the drug for congestive heart failure. Why are Americans willing to help consumers access medicine to alleviate the common cold or a headache and not lower insulin costs to keep people alive? Do springtime runny noses take precedent over life-threatening illnesses?

Because of this counterintuitive situation in which patents prevent development of generic life-saving drugs, consumers try to save money by resorting to dangerous practices, including drug rationing and using "Me-too" drugs slightly altered to avoid patent infringement. Ideally, a diabetic would make decisions about his insulin dosage based on food intake and blood sugar sliding scales. For example, if a diabetic patient needs to administer larger doses to regulate their blood sugar, s/he may run out of medication before a prescribed refill. Medications based on changing factors, such as insulin, require flexible dosages. If a diabetic person needs an insulin refill sooner than allotted period, he must pay more. Or more commonly, patients cannot afford their medications when it is time to refill prescriptions. Both inconveniences happens so frequently that diabetics ration their insulin supply to avoid paying large prices. When a diabetic rations his insulin they risk pushing their body into diabetic ketoacidosis, which shuts down the body's vital organs until death.

In addition to drug rationing, many patients resort to "Me-too" drugs and thereby risk introducing foreign drugs into their system. Unlike generics, "Me-too" drugs are bio-similar drugs that possess a similar chemical composition to that of the prototype (Garattini, 1997). "Me-too" drugs are mistaken for generic drugs, but they are in no way congruent. Mario Negri investigates "Me-too" drugs "potentially dangerous trend because [that trend] undermines what should be the main goal of drug development, for example to make active medicinal agents available to the patient with precise and reliable information" (Garattini, 1997). "Me-too" drugs have an identical mechanism of action but are principally old drugs chemically modified and sold under a new name. For instance, Pradaxa (dabigatran), Xarelto (rivaroxaban), and Eliquis (apixaban) are all "Me-too" drugs based on Warfarin, which prevents and treats blood clots (Young 2015). The only "new" part of these "new" drugs are simply in name and offer no further differences or advancements in treatment capabilities than their predecessors. Unfortunately, "Me-too" drugs are not an innovative drug but rather another aspect pharmaceutical companies exploit.

Considering ascending prices and fruitless "Me-too" drugs, generics offer the perfect solution to the problem the chronically ill face. Generic drugs provide consumers a way to purchase their necessary medications at low costs. Medications that continually need to be filled can cost approximately \$500 to \$1,000 a month. Generics not only provide a low-cost option, but they also create competition in the drug market that forces name brand pharma companies to match their competition. The competition generates low costs on generics and name-brand drugs, which is beneficial for all, "especially in a national health system that supplies drugs to patients who have too low an income to pay for them" (Garattini, 1997). Healthcare insurance can offer more coverage and the federal government is able to extend help to more people. Pharmaceutical patents need to be reformed to allow the manufacturing of generic drugs.

The national government regularly intervenes when it comes to environmental issues yet not when it comes to patient health. An active government should show a greater interest in protecting patients' wellbeing, which is why patents should be limited. The carbon footprint of large monopolies are monitored so the national government can reprimand companies who pose a threat to the environment. It is time that the national government monitors the harms pharmaceutical patents have on the chronically ill. Patents should have a permanent expiration date. Once the patent on a drug expires it should not be renewable and should be placed in the public domain. The public should have access to create generic forms of name brand drugs. Expiring patents inspires innovation in the drug market. Pharmaceutical monopolies must design new, innovative drugs to generate revenue. Now pharma monopolies work for profit rather than hide behind the fraud of reclaiming old drugs as new ones. By limiting patent renewals, generics present the perfect solution to rising drug prices.

Clearly the effects of pharmaceutical monopolies' tight control of pharmaceutical patents financially and physically harms consumers. Introducing generic forms of life-dependent drugs is beneficial for consumers, pharma monopolies, and the federal government. Generics supply a low-cost solution in a high-cost drug market, inspire drug innovation within pharmaceutical monopolies, and offer a means for the federal government to extend healthcare aid. Although pharma monopolies abuse of pharmaceutical patents they provide the necessary drugs for life. Therefore, restrictions are required to stop the exploitation of chronically ill consumers.

References

- Bliss, M. (2017). *The discovery of insulin*. Toronto, Canada: University of Toronto Press.
- Dumit, J. (2012). *Drugs for life: How pharmaceutical companies define our health*. Duke University Press.
- Feldman, R., & Frondorf, E. (2017). *Drug wars: How big pharma raises prices and keeps generics off the market*. Cambridge University Press.
- Gabriel, J. M. (2014). *Medical monopoly: Intellectual property rights and the origins of the modern pharmaceutical industry*. University of Chicago Press.
- Gandel, S. (2015). *Valeant: A timeline of the big pharma scandal*.
<https://www.ncbi.nlm.nih.gov/pubmed/9442441>
- Garattini S. (1997). *Are me-too drugs justified?* <http://fortune.com/2015/10/31/valeant-scandal/>
- Greene, J. A. (2014). *Generic the unbranding of modern medicine*. John Hopkins University Press.
- Young, K. (2015). *Pharma heavily markets "me-too drugs" to physicians*.
<https://www.jwatch.org/fw109727/2015/01/09/pharma-heavily-markets-me-too-drugs-physicians>

