The international standard for the length of patents on new medicines is twenty years. That standard was set by the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights, known as the TRIPS Agreement, which we learn more about in chapter 18. For essential medicines, that twenty-year monopoly guarantees two things: high prices for patent-holders and the resulting barriers to treatment for patients. But pharmaceutical corporations are rarely content with even a twenty-year monopoly on the medicines they sell, so they engage in a variety of tactics to extend that period.

From the perspective of for-profit corporations, the reasons for pursuing extensions are understandable: when a branded medicine goes off-patent, generic alternatives can come on the market, usually priced at a fraction of the branded version. At that point, the sales of the branded medicine can drop by as much as 90 percent or more.¹

For some pharmaceutical corporations, that sales drop is the equivalent of falling off a financial cliff. For example, the allergy drug Claritin accounted for one-third of the revenues of Schering-Plough before it went
off patent; in addition, Prozac once provided more than one-quarter of the revenues of Eli Lilly.\(^2\) Delaying that huge financial hit by extending a patent for even a few months or years can mean hundreds of millions of dollars to a pharmaceutical company. When the corporation Celaphon achieved an extension of its monopoly on the sleep-disorder drug Provigil in 2006, the company CEO was barely able to contain his excitement: “We were able to get six more years of patent protection. That’s $4 billion in sales that no one expected.”\(^3\)

So it is not surprising that pharmaceutical corporations are eager to hire what some industry observers call “floors full of lawyers” to pursue patent extensions. Here are some of the corporate tactics that are used to prolong monopoly patents—and the high medicine prices that go along with them: evergreening, data exclusivity, patent thickets and patent linkage, and buying off competitors.

**Evergreening**

Evergreening occurs when a new patent is granted for minor revisions or new uses of an already patented medicine, thus extending monopoly control past the original twenty-year period.\(^4\) Evergreening is also sometimes referred to as secondary patenting. One study showed that secondary patents block generic competition on average more than six years, providing monopoly extensions that earn corporations—and cost patients—billions of dollars.\(^5\)

Here is an example of how it works. In South Africa, the company Novartis obtained a patent in 1993 for the drug imatinib, a treatment for chronic myeloid leukemia that is marketed by the company under the name Gleevec. Before that South African patent was scheduled to expire in 2013, Novartis obtained two additional patents on the drug: one in 1997 for a new form of the compound and one in 2002 for the use of the drug to treat an HIV-related infection. The drug is now on patent in South Africa until 2022, twenty-nine years after the original patent was granted. In contrast, in India, where evergreening is blocked by its patent laws, there are no secondary patents on imatinib. The medicine is available in generic form, and costs 91 percent less than the South African version.\(^6\)
The evergreening process is quite common, especially with drugs that are big sellers, even though this approach completely contradicts the self-promotion of the pharmaceutical industry as a force for innovation and new treatments. The practice of evergreening, combined with the “me too” market-chasing focus of drug development, is the reason behind a startling fact: most new chemical entities patented by drug companies do not provide any new treatment value to patients. Researchers call that value therapeutic innovation, and precious few drugs offer it. One recent analysis estimated that 70 percent of newly marketed drugs offered no additional therapeutic value. Similarly, a 2009 European Commission study found that 87 percent of the medicine patents recently granted or pending in the European Union countries were secondary patents, most likely in pursuit of evergreening.

Although insulin was first patented in 1921, it is currently not available generically in the United States, setting the stage for the three manufacturers of insulin to raise their prices more than 160 percent in recent years. Costs for U.S. diabetes patients are six times higher than in other developed nations. A contributing factor to the prohibitive pricing has been the numerous patents insulin manufacturers have obtained on changes made during the ninety-plus years since its original discovery. There is debate over the relative value of those patented improvements. “I don’t think it takes a cynic such as myself to see most of these drugs are being developed to preserve patent protection,” David Nathan, a Harvard Medical School professor, told the Washington Post in 2016. “The truth is they are marginally different, and the clinical benefits of them over the older drugs have been zero.” The U.S. publication Business Insider entitled a 2016 article about insulin pricing, “A 93-Year-Old Drug That Can Cost More Than A Mortgage Payment Tells Us Everything That’s Wrong With American Healthcare.”

Data Exclusivity

Another patent-extending approach is for corporations to push for lengthy periods of data exclusivity to be inserted into national laws or international trade agreements. To understand data exclusivity, it helps to recognize that there are actually two separate processes that allow
pharmaceutical companies to block competitors. The first is the patent system, which we have already discussed. The second is exclusivity, a period of time in addition to the usual twenty-year patent period during which no generic competition is allowed. Exclusivity is granted by a government agency—in the United States, it is the FDA.

The key form of exclusivity is known as data exclusivity. Here is how it works. When generic manufacturers apply for the right to distribute a drug, they need to show that the drug is safe and effective. An obvious way to demonstrate safety and efficacy is to cite test results on the identical and previously approved patented medicines. But data exclusivity blocks generic manufacturers from doing so.\(^\text{13}\)

Without access to that test information, generic manufacturers are delayed in bringing their product to market, extending patent drug monopolies. The generic manufacturers may even have to repeat clinical trials on human subjects. That testing is not only expensive and time-consuming, it is unnecessary—because the drug has already been proven safe and effective—and thus ethically suspect.\(^\text{14}\)

Data exclusivity periods are shorter than the twenty-year baseline length of patents. In the United States, most drugs have five years of data exclusivity, and biologics have twelve years. So why do drug companies still pursue them? The reason is that data exclusivity periods do not begin until the drug receives market approval, which may be several years after the company has obtained its patent. So if a biologic drug was patented ten years before it receives market approval, the corporation has only ten years in which to sell its drugs under a patent-protected monopoly. But a twelve-year data exclusivity decision gives the corporation an extra two years beyond the patent expiration to sell without generic competition.

One bizarre case from 2009 illustrates the difference between a patent and exclusivity. A pharmaceutical corporation conducted a one-week clinical trial on a medicine for gout that had been widely available since the nineteenth century. The corporation could not get a patent for the medicine, but the clinical trial allowed it to apply for and receive a period of data exclusivity. It used the exclusivity to force competitors out of the market, after which it raised the price of the medicine by 5,000 percent.\(^\text{15}\)

The Obama administration has estimated that a five-year reduction in the twelve-year length of U.S. data exclusivity for biologic drugs would save federal health programs over $4 billion.\(^\text{16}\) Think of what else that
calculation means: the current data exclusivity rules now allow that extra $4 billion of taxpayer funds to be pulled in by monopoly drug pricing, along with a huge amount of direct costs shouldered by patients.

So it is no wonder that the pharmaceutical industry values data exclusivity so highly. As we learn in the conclusion to the book, the dogged pursuit by the industry of lengthy exclusivity for biologic drugs in the TPP became a sticking point in the debate over the trade deal.

**Patent Thickets and Patent Linkage**

Patent thickets, also known as patent clusters, are exactly what those nicely descriptive terms suggest they are: a dense pack of patents drafted by the “floors full of lawyers” to surround medicines that generate profits for pharmaceutical corporations. Would-be generic competitors must navigate that thicket of patents—one study found as many as 1,300 patents on a single drug—before they can offer their low-cost alternatives to patients.\(^{17}\)

*Patent linkage* is the term for national laws or trade agreement terms that provide the platform for patent thickets to do their work. Linkage laws require generic competitors to prove that their product does not violate any of the hundreds or even thousands of patents protecting a monopoly drug. Even though many of those patents are quite suspect, linkage laws create a huge, time-consuming, and costly task list for would-be generic competitors to accomplish.

Together, thickets and linkage are quite effective at fending off generic competition. For example, the corporation AbbVie has a reported seventy-plus patents on its arthritis drug Humira, and these additional patents should add at least six years of monopoly protections on to the original Humira patent period. “Any company seeking to market a biosimilar version of Humira will have to contend with this extensive patent estate, which AbbVie intends to enforce vigorously,” Richard A. Gonzalez, the AbbVie CEO, said in 2015.\(^{18}\)

The motivation for these efforts is no mystery. Humira is the top-selling prescription drug in the world, and its $14 billion in sales in 2015 accounted for more than 60 percent of the total revenue of AbbVie.\(^{19}\) Every day that AbbVie can extend its monopoly represents millions of dollars in revenue for the company.
AbbVie is far from alone in exploiting patent thickets. A 2010 study published in the *Northwestern Journal of Technology and Intellectual Property* examined multiple examples of the tactic and concluded, “The linkage regulation regime in particular has proven to be an excellent vehicle for firms to obtain extended legal protection on drugs at all stages of development, including drugs about to come off patent protection.” Economists call this activity by patent-holders rent-seeking, so named because it seeks to collect revenue without producing anything new or useful. Under rent-seeking, innovation takes a back seat to protecting monopolies. “[Pharmaceutical] companies today have found that the return on investment for legal tactics is a lot higher than the return for investment for R&D,” said one health insurance executive. Do not look for that statement to be repeated on any PhRMA public relations material anytime soon!

**Buying Off Generic Competitors, AKA “Pay for Delay”**

Patent thickets and patent linkage provide pharmaceutical corporations with significant leverage that allows them to engage in what one commentator called a “sleazy and blatantly self-serving” patent extension tactic: buying off would-be generic competitors.

A company that wants to sell a generic version of a drug that is coming off its original patent faces a significant problem: before it can sell its product, it probably has to overcome costly, years-long, thicket-citing lawsuits filed by the deep-pocketed, highly motivated corporation that holds the patent(s). But there is another, less onerous option for the generic competitor, known as “pay for delay.” The generic company can, instead, accept a large check from the patent-holding corporation in return for an agreement to delay its entry into the market.

There is a clear mutual incentive for such a deal. Because the generic company would sell the medicine at a sharply reduced price, its limited expected profits can be easily matched or exceeded by a big check from the patent-holding corporation. For the patent-holder, that check amount is still less than the company would lose by surrendering the monopoly that allows it to mark up the price tag of the drug to a level far above what the generic company would charge. Both companies win. The only
loser is the patient, who is still forced to pay the monopoly price for the medicine she needs.

Remarkably, pay for delay is arguably legal in the United States, despite recent efforts by the Federal Trade Commission (FTC) to ban the practice as a violation of the antitrust laws. The U.S. Congress has not been any help in that effort—remember the heavy lobbying and campaign expenditures by the pharmaceutical corporations?—and a 2013 U.S. Supreme Court decision did not fully clarify the issue. Meanwhile, as Jon Leibowitz, former FTC chair, has characterized the current status quo, “Instead of competing to be first to come to market, generic companies compete to be first to get paid off.”

These industry tactics can get a bit difficult to keep track of, so it is important to remember why they matter: they are all corporate schemes whose aim is to prevent us from accessing generic medicines, which can be anywhere from 40 to 90 percent cheaper than the patent-protected medicines. So the impact of pay for delay, along with evergreening, packet thicket, and patent linkage, is enormous. A 2012 study found that eliminating just evergreening in the United States could allow over one-third of currently patent-protected medicines to be immediately open to generic competition. Barring evergreening would also reduce by four or five years the delays in other patented drugs being open to competition. As for pay-for-delay schemes, the FTC estimates they cost U.S. patients an extra $3.5 billion each year.

Of course, for patients who cannot afford the cost of monopoly-protected medicines, whether they live in the United States or in other countries, patent extensions are not measured in dollars and cents. Their impact is felt in sickness, suffering, and even death.