

ANSWERING THE CRITICS OF PHARMACEUTICAL PATENTS

By Dr. Merrill Matthews Jr.

Of all the recent criticisms leveled at the prescription drug industry, the one that has resonated most with the media, politicians and the public is that drug companies are gaming the patent system.

The critics have been so effective because patent law and intellectual property (IP) are inherently murky subjects. As a result, critics can repeatedly (and falsely) claim that when a brand name, or “innovator,” drug company sues a generic manufacturer for patent infringement, the innovator company receives a 30-month patent *extension*. Few outside the drug industry understand the error, and the media won't listen to them. Drug companies get as much as a 30-month *stay*, not a patent extension, which stops the generic manufacturer from marketing its product so that the dispute can be resolved.

Yet the myth persists that brand name companies are greedily sidestepping the law. And few consider the possibility that generic manufacturers might be infringing patents to maximize *their* profits. The object of this brief paper is to bring some balance to this lopsided debate.

Criticism #1: Patents on prescription drugs create a monopoly that keeps lower-priced generic drugs off the market. When ABC newsman Peter Jennings hosted a one-hour attack on the innovator drug companies called “Bitter Medicine,” he simultaneously claimed that patents create a monopoly for drug companies, thereby squelching competition, *and* that there are currently 170 drugs, both patented and generic, on the market for high blood pressure.

So which is it: monopoly or rampant competition?

Granting a patent on a product means that others can't copy that product; but other companies may produce something addressing the same medical condition. Although Vioxx and Celebrex have dominated the new and growing market for the pain medications known as COX2 inhibitors, others are near FDA approval and many more

are in the development pipeline. Even a company with a patent can face serious competition from other drugs.

Criticism #2: Patents keep drug prices high, limiting low-income people's access to brand name drugs. This may be the most pernicious of the accusations, since drug companies have gone to great lengths to ensure that low-income people, both here and abroad, have access to prescription drugs.

Most companies have drug assistance programs that help low-income people obtain the drugs they need at greatly reduced prices or free. In 2000, for example:

- Industry assistance programs provided \$1 billion worth of medicine to 2.4 million patients.
- Three drug companies donated 100 million doses of polio vaccines to poor countries in Africa.

But many drug companies have gone a step further. In the fall of 2001, the company now called GlaxoSmithKline introduced its Orange Card program, which lets qualified low-income seniors buy the company's drugs at discounts of roughly 25 to 40 percent. Novartis announced a similar program a month later. Then in January 2002, Pfizer introduced its Share Card program that allows qualified low-income seniors to purchase a month's supply of any Pfizer drug for just \$15. By the end of 2002:

- 250,000 low-income seniors had enrolled;
- 1 million prescriptions had been filled; and
- 31,000 retail pharmacies were accepting the card.

Shortly after Pfizer began its program, Eli Lilly kicked off a new program allowing low-income seniors to get any Lilly drug for \$12 a month. And seven companies have joined to create the “Together Rx” discount card program.

Of course, the brand name companies also give away about \$10 billion annually in free samples, which doctors often channel to low-income patients to save them money.

Criticism #3: Brand name drug companies go to extremes to extend their patents beyond their established life. The federal government grants patents for 20 years — no more, no less. In most industries, the “effective patent life” — the amount of time a company has to actually market a product — is 18.5 years. For pharmaceuticals, the effective patent life is only 11 to 12 years. That’s because it takes so long to develop and test a new drug and then get it through the FDA approval process.

Federal legislation does permit an additional six-month exclusivity period if an innovator goes to the additional effort and expense of testing a drug in children and getting FDA approval for that population. In addition, the government lets drug companies recover up to five years of the patent life they lose as drugs move through the FDA approval process. But those are options legally available to innovator companies, not attempts to game the system.

Criticism #4: Innovator companies are filing frivolous lawsuits to keep generics off the market. Under the 1984 Hatch-Waxman Act, a generic company gets a 180-day exclusivity period if it is the first to announce that it will introduce a generic version of a brand name drug when it goes off patent. If the brand name company believes the generic is infringing its patent, it has 45 days in which to file suit. If it does, a stay may be imposed prohibiting the generic from going to market for up to 30 months. But this is a *stay*, not a patent extension. If the patent runs out in that 30-month period, the lawsuit becomes moot.

What the 180-day exclusivity period really does is provide generics with a strong financial incentive to infringe an innovator’s patent, something Congress never intended. Originally, a generic only received the exclusivity period if it were first to announce, was sued and won the suit. Today, a company only has to be the first to announce it will market the generic. If Congress were to return to the original idea, generics would have less incentive to attack another company’s intellectual property.

Criticism #5: Strong intellectual property laws hurt the poor. If this assertion were true, then those countries with the strongest intellectual property laws would have the poorest populations and vice versa. Of course, just the opposite is true. Those countries with the strongest IP protections are by far the most prosperous economies. Why? Creators create because their investment and efforts are protected. And those efforts create jobs that grow the economy.

Economic growth occurs where property, both real and intellectual, is protected. Would major companies set up shop in countries where people were allowed to walk into the business and take whatever they wanted, just because they said they needed it? Yet that is exactly what is happening with regard to intellectual property in many third world countries.

Why Do Innovators Get Bad Press and Generics Good Press? There appears to be a tacit assumption in the media and among many politicians that brand name companies are motivated only by profits and a selfish desire to protect their patents, while generic manufacturers have only the public good in mind. Yet a *USA Today* article has pointed out that some generics challenge existing patents in the hope of settling out of court, never actually intending to go to market. It’s part of their business model and a source of a significant portion of their profits.

In addition, CBS News recently reported that the price of “Some generic versions of popular medications have climbed more than 1,000 percent in the past year.” And an ABC affiliate in Detroit discovered that some pharmacies were marking up generics by 3,300 percent!

Conclusion. Generics play an important role in providing access to less-expensive older drugs. But generic manufacturers’ efforts to weaken intellectual property protections and the critics’ continual attacks have created a perception that innovators are gaming the patent system. While a few innovator companies may have pushed the envelope to protect some patents, generics also have a significant financial incentive to challenge the brand name companies and their intellectual property.

In a market the size of prescription drugs, it is simply naive to assume that brand name companies are selfish and side-stepping the rules while generics and other players always have the best interest of patients at heart.

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