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FROM THE IPI CENTER FOR TECHNOLOGY FREEDOM September 9, 2002

# Is There a Good Monopoly?

*By Richard A. Epstein*

To most Americans "monopoly" is a dirty word used to describe rich corporations that take advantage of market domination to soak their customers. That legacy goes back to the late 1800s when industry giants tried to capture and control entire markets in order to charge more for their goods and services than they could have if eager competitors were vying for customers. The Sherman Antitrust Act of 1890 was passed to rein in business monopolies and give competition a fighting chance.

**A "Good" Monopoly?** However, some forms of monopoly power are not the products of corporate giants trying to eliminate competition, but are granted by the federal government to achieve a social good for society as a whole. That is the case with patents, under which the federal government grants to inventors an exclusive right to make and sell a product or process as a reward to induce and encourage their creative efforts.

Of course, patent holders, like monopolists in general, will attempt to charge more for a patented good or process than would be possible in a competitive market where there are several close substitutes. But that is the economic tradeoff we make in order to encourage innovation. If you remove the patent monopoly, the rate of new invention will taper, with the result that everyone would enjoy the hollow right to buy products that have not been created. The social challenge is to find the right balance between encouraging innovation and allowing competition.

It would be easy to give too much patent protection: a patent could last for hundreds of years; or patent protection could be described too broadly. But U.S. patent law has so far avoided these pitfalls by limiting patents to 20 years and by awarding them only for "nonobvious" advances over the prior art. In addition, the patentee must disclose to the world the best mode for making the invention, and thereby plant, as it were, the seeds for his own destruction.

**Competition and Monopoly.** The phrase "patent monopoly" is something of a misnomer. No drug patent, for example, protects its holder against the sale of a *different* patented pharmaceutical approved for the same medical condition. Indeed, if two manufacturers fixed prices for both drugs, their patents wouldn't save them from criminal punishment and treble damages under the antitrust laws. Thus, even if these two drugs are only imperfect substitutes for each other, their dual presence restrains prices for both products — assuming some superior new drug does not drive them both from the marketplace.

**Drug Prices Are Based on Costs and Risks.** The research-based pharmaceutical industry faces numerous obstacles and risks in bringing a new drug to market. One distinctive risk is that years of their patent period are consumed in gaining Food and Drug Administration (FDA) approval — *after the patent has been obtained*. In addition, companies must be allowed to recoup their huge front-end investment, now estimated at about $800 million for each new chemical entity brought to market. In light of these costs and business risks, patent holders must be allowed to charge more than their marginal cost to manufacture a drug, plus a competitive profit.

**Hatch-Waxman: Striking the Balance.** To reduce the risk to drug patent holders, in 1984 Congress passed the Hatch-Waxman Act, which extended a patent life up to five years: a one-day extension for each two days that a patented drug was before the FDA.

However, Hatch-Waxman also gave manufacturers of generic equivalents some real advantages. They may rely on the clinical tests of the original proprietary manufacturer in obtaining their own FDA approval, so long as they can show chemical identity and bioequivalence (i.e., the active ingredient is absorbed at approximately the same rate) for the generic version of the drug. Generics are also allowed to conduct experimental manufacture and use of the drug while the old patent is still in force so that they can market their product quickly once the original patent expires. Finally, the first generic to gain FDA approval receives a

180-day exclusive marketing period over other generics for introducing a rival to the patent drug.

Sometimes a generic manufacturer will, prior to the expiration of a patent, seek to bring its own product on the market by claiming that the basic patent is either invalid or not infringed. If so, then the holder of the proprietary patent is allowed an automatic 30-month stay (if the patent runs so long) provided it alleges the infringement of its valid patent.

Hatch-Waxman was a sophisticated compromise among proprietary manufacturers, generic manufacturers and the public at large. It spurred substantial levels of investment in new drug research — up from $4 billion in 1985 to more than $30 billion (domestic and foreign) in 2001 — while ensuring a steady increase in generic drugs as brand-name drugs go off patent.

**Destroying the Balance: The Reid Amendment.** Unfortunately, this balance would be disrupted under legislation passed by the Senate. The most ominous of the new proposals comes from Senator Reid (D-Nevada) in a proposed amendment to the "Greater Access to Affordable Pharmaceuticals Act of 2002" (S.812). His legislative fix is not a direct attack on patents. Rather, it is promoted as a means of supplying "affordable" pharmaceuticals to all Americans, especially seniors and the disabled.

The Reid Amendment works in two steps. The first prohibits any form of price discrimination; i.e., charging different prices to different customers for the same drug.

Of course, price discrimination is common with patents because some buyers are willing to pay more than others, and it does not violate the antitrust laws so long as each patent holder does it on his own initiative.

Moreover, price discrimination allows more people to purchase a product or service. If higher prices can be collected from at least some users — so that the initial costs of drug development can be recovered — then manufacturers can charge lower prices to those who have fewer means. By eliminating price discrimination, the Reid Amendment appears to hurt "low demanders" (i.e., those with fewer resources) and to help high demanders of the good.

But the second step is the killer. Not only does the Reid Amendment eliminate price discrimination, it also forces the drug manufacturer to sell any patented product to all customers at the lowest price it is sold or offered to any domestic or foreign customer (sales to charitable and humanitarian institutions are excepted). Thus:

- One sale to a rural medical clinic under a long-term contract would trigger price reductions to all buyers everywhere.
- A forced sale ordered by a foreign government could slash the price of every sale in America.
- Any voluntary deep-discount sale of AIDS drugs to African or Asian governments would do the same.

The Reid Amendment turns drug pricing into an administrative nightmare, while research-based pharmaceutical houses are denied any opportunity to recover their research costs, including the cost of developing drugs that don't make it to market.

**Is the Reid Amendment Constitutional?** As a matter of constitutional law the Reid amendment should be struck down under constitutional principles that developed side-by-side with the antitrust laws. At stake here is confiscation by regulation. Some industries must spend millions before they can earn a dime. For example, a power plant that costs $1 million to build can supply, once built, a kilowatt of electricity for $1. If the regulator allowed the power company to charge only $1 per kilowatt, then the firm would never recover its initial construction costs. To protect that investment, the courts require the regulator to set prices high enough to allow the firm to recover its initial investment over the life of its power plants.

Sound familiar? The power plant is analogous to the patented pharmaceutical. The $1 per kilowatt charge is analogous to the $1 generic equivalent. In both cases, constitutional protection against confiscatory rates encourages the initial investment by securing its return thereafter.

**Conclusion.** New drug development is needed to take us to the forefront of medicine. But the constitutional principles established for regulated industries in the age of iron and steel are still applicable and should strike down the Reid Amendment's attempt to deprive pharmaceutical companies of a return on their investments. Congress may be able to impose recklessly these price restrictions on future research, but, if it does, then it will have to explain to the American public why the next generation of wonder drugs was never invented.

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