

Pharma 'patent trolls' remain mostly the stuff of myth

"Sometimes, it's like the patent discussion has degraded into a third-grade name-calling contest... 'na, na, na, you're a troll,'" says Daniel Ravicher, executive director of the not-for-profit legal advisory organization the Public Patent Foundation, an organization that most likely has never been compared to this type of mythical creature.

What many call 'patent trolls' are most properly referred to as nonproducing entities, or NPEs. They're typically defined as companies or individuals that hoard patents not for actual use, but simply as tools to squeeze other companies for lawsuit settlements and licensing fees. They operate within the law and yet pose a big problem for high-tech industries. Legal actions can take successful technologies off the market and drain money that often would be otherwise devoted to research and development. However, thus far, NPE-type activities have been relatively absent in the pharmaceutical industry—though some predict this could change.

"We need to look honestly at these perfectly legal companies, because they're an element of a patent system that is becoming more and more abused," says Ravicher.

Pejoratively, the simplest abstract example of an NPE would be a group of lawyers with a bank account and catalog of patents, explains Chris Reohr, cofounder of Patent Freedom, a company that tracks NPEs. The most commonly cited case of what's typically

referred to as NPE litigation, however, is the 2006 US Supreme Court case *eBay, Inc. v. MercExchange, LLC*, in which the latter had an extensive catalog of unused patents that described web-based tools for online auctions, including one that covered eBay's 'Buy-it-Now' function. The case set a legal precedent for how courts should deal with NPE-type companies. What's more, it implemented a set of rules that had the result of limiting NPEs' bargaining power. Nevertheless, such activity continues to grow.

According to Patent Freedom's estimates, the percentage of patent lawsuits involving NPEs has risen from just 2% in 1998 to 13% in 2008. The jump has even been cited by the Obama administration as a need for patent reform. However, the boom has been almost entirely within high-tech industries involving computer hardware and software. Patent Freedom's system of charting litigation has yet to pick up on any litigation specifically relating to pharmaceuticals.

Matthew Rimmer, a senior lecturer at the Australian National University in Canberra and author of *Intellectual Property and Biotechnology*, says that NPEs are much more troublesome in the field of information technology (IT), because an individual IT product tends to have many components that would require many patents. So, it's easy for an NPE to have one vague patent that may cover one aspect of another entity's device

or software. Pharmaceuticals, in contrast, tend to deal with products that have one patent for one arduously researched chemical. Further protection of pharmaceuticals in the US is provided by the country's issuance of data exclusivity by the Food and Drug Administration and by regulation of generic drugs.

Stanford University law professor Mark Lemley adds that, although no one would call them NPEs, university-associated institutions sometimes have an NPE-like role in the pharmaceutical industry by aggressively enforcing patents they hold. For example, in a 2006 working paper (Stanford Public Law Working Paper No. 980776), he cites the Wisconsin Alumni Research Foundation's rigorous enforcement of stem-cell patents, among others.

The pharmaceutical industry almost always comes down on the side of patent law that strengthens patent enforcement (and, thus, the ability of NPEs to practice). However, Rimmer says that even the pharmaceutical industry may not be able to maintain its NPE immunity for very long.

"It's not the definition of an NPE that counts. It's the larger problem that patents are becoming less about actually protecting innovation and more about exploitation," Ravicher says. "Don't count on that changing any time soon."

Stu Hutson, Gainesville, Florida



Researchers ponder a patent-free world

Patents are safeguards of intellectual property—a centuries-old institution written into the US Constitution. Yet, when it comes to pharmaceuticals, the system has been accused of smothering, rather than supporting, innovation while withholding lifesaving discoveries from those who need it most.

"The standard belief was that you need property rights to support innovation," says David Levine, an economist at Washington University in St. Louis, "but when we looked at the empirical literature on patents, we found that wasn't true." His research with colleague Michele Boldrin indicated that patents actually inhibited innovation, as in the case of Italy. They wrote that prior to 1978 the country had no patent protection, yet it was the fifth world

producer in pharmaceuticals and the seventh exporter, discovering 9.3% of the world's new active chemical compounds. After patent law was enforced, that percentage dropped to 7.5% (Boldrin, M. & Levine, D. *Against Intellectual Monopoly*. Cambridge University Press, New York, 2008).

However, Levine does concede that patents protect against the huge costs incurred from developing new drugs. "You can't expect someone to spend a billion dollars on a venture if everyone then gets to have it for free," he says. But he adds that this could be avoided by restructuring costly phase 3 trials.

Levine proposes an auction system for the trials, in which competing testing agencies could bid for royalty rates. The company that bid the lowest royalty rate

wins the right to run the trial and develop the drug.

Another alternative to patents that still creates incentives, proposed by Nobel Prize-winning economist Joseph Stiglitz of Columbia University, awards money to drug innovators (*BMJ* **333**, 1279–1280; 2009). The big prizes would go to the drugs that help many people. All formulas and instructions would be made public, making the drugs affordable and easily available.

"The prize idea has some merit," says Lou Berneman, former director of the University of Pennsylvania's Technology Transfer department, "but, practically, this won't work."

"There would be no exclusivity available, thereby depriving innovative companies protection to their huge investments," Berneman adds.