

The U.S. Chamber of Commerce
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Global public health needs demand continued investment in research and development related to Type II and Type III diseases, in addition to the specific research and development needs of developing countries, in relation to Type I diseases. Resolution WHA61.21 on the global strategy and plan of action on public health, innovation and intellectual property, in particular paragraph 4(7), requests the Director-General to examine current financing and coordination of research and development. We strongly support the Director-General's efforts in this area. With respect to the reference language requesting the Director-General to examine "new and innovative sources of funding" we also support this effort, but would caution against attempts to replace, rather than complement, proven incentive systems for attracting new R&D investment.

Some parties claim that the existing global patent system embodied in national laws and international agreements are not only insufficient to drive innovation in key sectors, but that they also fail to deliver new technologies at reasonable prices – particularly in the developing world. For these reasons, they say that patents should be *replaced* with government prizes, patent pools, or other incentive mechanisms that offer public ownership and access to new technologies and inventions.

While prizes and patent pools have become useful supplements to patents in certain circumstances, limited incentives in stimulating innovation and technology diffusion make them risky alternatives for a proven intellectual property (IP) system.

Evolving Supplements

Prizes and patent pools have long been used to drive innovation and the development of new products in the United States and in many other countries around the world. Whether offered by governments or by wealthy individuals, cash prizes have provided strong financial incentives for creating a needed technology or for proving that a certain feat is possible.

Cash prizes brought us margarine and canned vegetables and rewarded Charles Lindbergh's first nonstop transatlantic flight. Over the years, these incentives have evolved to reflect the increasing cost and complexity of modern invention. For example, the 2004 Ansari X Prize—the largest prize in history—granted \$10 million to the team that built the first private-venture spacecraft. A 2007 amendment to the Food and Drug Administration Act grants "priority review vouchers" to firms that develop new drugs for neglected diseases in the developing world. Those firms may sell the vouchers to others, potentially making them another form of cash reward.

Patent pools have also produced important results and have evolved to meet new global challenges in a changing marketplace. Historically, pools have formed when two or more companies agreed to cross-license their patents on particular technologies and to create a single facility for all licenses needed to use and build on prior inventions. Such consortiums can be instrumental in enabling innovators to develop new products when those products must be based

on multiple existing inventions covered by patents owned by more than one company, or on an invention with multiple components covered by one or more patents.

Patent pools formed to produce better sewing machines in the 1800s and new combat aircraft during World War I. More recently, they have powered the development of radio frequency identification (RFID) and certain digital compression technology (MPEG2). In 2008, member companies of the World Business Council for Sustainable Development established the Eco-Patent Commons to pool and make certain patents available without royalties for innovations that provide environmental benefits.

Poor Substitutes

Prizes and patent pools may help supplement the patent system, but they are imperfect substitutes at best. Indeed, these tools are embedded in and often rely on the very IP system that some of their proponents would like to see them replace. Legislation introduced in the 110th Congress would have established a prize fund to reward manufacturers of new medicines, but would have still used patents to block competitors from introducing rival products during the regulatory approval process. Though useful in specific circumstances to solve or overcome particular problems, prizes and patent pools also suffer from numerous drawbacks, which may help explain why they have been used so rarely.

The impact of prizes is sharply limited by their size, scope, and nature.

- Prizes large enough to truly replace patents as incentives for the development of innovative new products in many cutting-edge and highly regulated fields would impose significant up-front costs on taxpayers. According to some studies, it can cost as much as \$500 million to \$800 million just to secure FDA approval of a new medical treatment, let alone cover fixed research and development costs.
- Prizes are better at proving a concept than bringing concrete, useful technologies to market. Even the Ansari X Prize did not deliver a commercially viable product. That task fell to Virgin Galactic, which licensed the patented technology for which the prize was awarded and is expected to invest upward of \$100 million to develop the spacecraft for commercial use.
- Prizes can result in actions and products tailored to narrow and predetermined parameters, but they will never be sufficient to reward the unexpected lucky breaks that have delivered some of the most significant—and often highly disruptive—inventions. When it was first introduced, Alexander Graham Bell’s “electrical speed machine” was a novelty with no proven practical application. Today, we know it as the telephone. To conceive of an outcome worthy of a prize, the state of the art must already be a long way toward realizing it.
- By itself, any power a prize may have often stops at the moment it is awarded. Whether it comes in the form of a one-time payment or is spread out over a period of years, prizes do not create the incentives necessary to drive a continuous cycle of critical advances and

improvements. Under existing U.S. law, medicine manufacturers can acquire new patents on existing drugs when they (or clinicians) discover new applications for those treatments—something that happens frequently. In 2008, for example, researchers at the University of Oklahoma found that a cholesterol drug approved 15 years earlier significantly lowered hepatitis C viral loads in infected patients. Without patents, there would be fewer incentives to find new uses for lifesaving drugs already available.

- By focusing narrowly on spectacular acts or on the next new thing, prizes can distract from more effective solutions. Often, the hardest part of managing global challenges is not developing breakthrough products but scaling existing technologies and changing business and individual behavior. Despite the global focus on new environmental technologies, many experts believe that one of the best ways to reduce carbon emissions is to convince individual consumers to conserve fuel and power and switch to existing energy efficient lighting and appliances.
- Perhaps, most importantly, prizes do not hold researchers and inventors accountable for the results of their discoveries and creations. Specifically with respect to the production of medicine, innovative drug manufacturers invest huge sums to develop, test, approve, produce, and distribute new lifesaving treatments. Through the entire process, they remain responsible for their products—giving them a powerful incentive to ensure their safety and efficacy. As some proponents have explained prizes, they would result in the transfer of rights from the inventor of a product that won the prize to the government that offered the prize. The government would then put those rights in the public domain, making it all but impossible to determine who is responsible for any problems down the road.

Patent pools are also not without their flaws. These tools are similarly limited and can result in nearly as much litigation as they prevent.

- Patent pools have also been criticized for eliminating competition and for encouraging the kind of collusion that is the very enemy of access at reasonable cost. In a landmark U.S. legal case, involving a pool of patented technologies related to the manufacture of glassware, courts found that participants used the pool to limit the types (and, in some cases, the quantity) of products licenses could produce and to prevent newcomers from entering the field.
- Patent pools can actually enable monopoly pricing and inflate the cost of goods or technology by reducing the incentives of participating right holders to produce alternatives. In another U.S. legal case, the Supreme Court found that the United States Gypsum Company had entered into a series of patent licensing agreements intended to fix the price of patented gypsum board (a common construction material), eliminate the production of unpatented board, regulate the distribution of patented board, and stabilize the price of unpatented plaster.
- Patent pools may shield rights that otherwise may have been invalidated through a court case brought by a competitor participating in the pool. This may happen, for example, if

a firm with a weaker patent claim entered into a cross-licensing agreement with a firm with a stronger claim, resulting in an arrangement whereby the firms avoid costly litigation between themselves and act together to defend both the stronger and weaker patents against other competitors. In such cases, the public could end up paying royalties or higher prices for a technology.

Prizes and patent pools clearly have served and can operate as useful supplements to patents in certain narrow circumstances. They have and, no doubt, will continue to evolve and be improved over time. But they must be used on a supplementary and voluntary basis with terms and conditions that are clear and agreed to by all affected parties.

By so tightly managing and controlling innovation outcomes, prizes and patent pools are unlikely to incentivize, reward, and deliver the breakthrough technologies, treatments, and inventions necessary to solve these urgent public health challenges. Indeed, if prizes and patent pools were inherently superior to patents alone, they would have already delivered groundbreaking innovative medicines. That they have not, despite long histories, widespread knowledge of their uses, and recent attempts, is perhaps the surest testament to their limitations.