

The Senior Center for Health & Security

Enhancing the Lives of Older Americans



What You Need to Know

A special educational series

Patent Protection

Ensuring the Innovative Path to Cures

Early in the U.S. Constitution, in Article 1, Section 8, where the powers of Congress are enumerated, intellectual property, protective patents, and their fruits are recognized by the Founders.

To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries;

Nowhere are those words and their impact more meaningful than in the research and development necessary to bring to market safe and effective medications to treat and cure the most deadly and debilitating diseases. Drug discovery, perhaps the noblest endeavor, is typically a time-consuming, frustrating, and expensive effort. On average it takes 10 to 15 years and costs \$800 million to \$1 billion or more to develop one new medicine from the time it is discovered to when it is available for treating patients.

These staggering numbers include, by necessity, the thousands of failures that are part of the process. Over a 3 to 5 year period, it takes 5,000 to 10,000 compounds in the drug discovery process to produce 250 for preclinical trials. From each of those 250 promising candidates, just 5 compounds reach clinical trials which are conducted over a 6 to 7 year period. Of those 5, only 1 survives to finally gain Food and Drug Administration approval, a process that can consume even more years. That's the drug discovery process, 5,000 to 10,000 compounds and years of work, risk, and expense to produce 1 new medicine.

Biologics, that have evolved to treat the deadliest and the rarest maladies, often take longer to develop, and cost even more than small molecule pharmaceuticals.

With this tortuous route to produce safe and effective treatments, strong patent protection for pharmaceutical and biopharmaceutical products on the market, and in development, is imperative. If that protection fails, innovation fails with it, and needed cures will never come to fruition. Billions of research dollars must be recouped and reinvested in yet more research and development. New treatments, better therapies, and critical cures are at stake.

For hundreds of small U.S. biotechnology firms, with no product yet on the market, the intellectual property they own is everything, the lifeblood that makes their ongoing research possible. Their patents must be protected or their unique innovation will be lost. Continued investments in their determined efforts can only be achieved with strong patent protection.

America cannot let self-serving interests cheapen patents through "apportioned" judgments or "prior art subtractions" that limit the courts' capacity to award the full, appropriate judgment to the infringed upon innovator; allow "second windows" that make secure patents impossible because of endless challenges; or allow the PTO Director to promulgate regulations that would weaken patents or supplant the courts. Patent infringers must be punished and discouraged, and countries or world organizations that attempt to steal intellectual property must be stopped.

Through the power of education, The Senior Center for Health and Security seeks to enhance the lives of older Americans. It works to promote the promise and potential of innovative medical research and development and to highlight its critical importance in ensuring seniors live longer, healthier lives.

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