

THE ALLIANCE OF U.S. STARTUPS
AND INVENTORS FOR JOBS



EXECUTIVE SUMMARY

The Importance of an Effective and Reliable Patent System to Investment in Critical Technologies

Written by Mark F. Schultz

July 2020



Executive Summary

The Importance of an Effective and Reliable Patent System to Investment in Critical Technologies

By Mark F. Schultz¹

Many of our nation's most important, innovative and dynamic breakthroughs have been the result of startup companies funded by venture capital. Nearly all of our leading-edge technology companies started as venture-backed startups and the U.S. biotechnology sector was born out of a relationship between venture capitalists and leading biochemists, most of whom are associated with universities.

The companies that have pushed the boundaries in critical new technologies have relied on an effective patent system to secure very risky and vastly expensive investments. That patent system is no longer as dependable as it once was.

In our forthcoming report, *The Importance of an Effective and Reliable Patent System to Investment in Critical Technologies*, we report new data that shows that as the

U.S. patent system has weakened, venture capital investment shifted away from patent-intensive industries. We supplemented our exhaustive review of 14 years of data tracking VC investment by talking to leading investors and innovators to find out why they might be less inclined to invest in and launch patent-intensive startups. In a series of case studies, they explain that changes to the U.S. patent system have made it less reliable and effective, driving investment of time and money away from critical technologies.

This policy brief previews our forthcoming report. Following the release of this report, USIJ will conduct a series of discussions with legal, policy and industry experts to develop a set of policy recommendations to deliver to Congressional and Administration leaders

Patent-intensive industries such as pharmaceuticals, medical devices, core wireless technologies and medical diagnostics require large investments over extended periods of time to bring products from concept to market. As we are learning daily, these are also the innovative industries our society relies on to address many of its most critical needs.

¹Goodyear Endowed Chair in Intellectual Property Law & Director of the IP & Technology Law Program, University of Akron School of Law. Research funding and support for this study was provided by the Alliance of U.S. Startups and Inventors for Jobs (USIJ). The views expressed in this Report are solely those of the author.

Never have these needs been more critical. The world is depending on researchers and life sciences companies who are racing to find treatments and cures for the Covid-19 pandemic. Nearly every development and clinical trial being led by U.S. life science companies has become headline news.

One of the innovative companies discussed in our report is Cleveland-based Convelo which is led by Dr. Derrick Rossi. Prior to serving as CEO of Convelo, Dr. Rossi's foundational stem cell research while leading a team at Boston Children's Hospital served as a basis for the founding of Moderna. Robert Langer, a serial entrepreneur at MIT and Noubar Afeyan, CEO of VC firm Flagship Pioneering, saw the immediate potential of the work being done and helped support the company's development.

Moderna is currently working with National Institute of Allergy and Infectious Diseases on an initial safety trial and has announced that it hopes to distribute a Covid-19 vaccine to health care workers this fall.

Never have the world's leading life sciences companies been so focused on a single goal, in a massive effort to save lives and restore a sense of safety and security to our daily lives. This effort relies on an innovative capacity that has been developed over decades. In many instances, it relies on drugs developed in the past — over 250 treatments or vaccines already approved to treat other diseases are in clinical trials to combat coronavirus..

Now, more than ever, we are reminded that we cannot and should not take our innovative capacity for granted. For decades, the reliability of patent protection made these investments possible and attracted innovators and entrepreneurs to take big risks to solve big problems. Investors require secure, stable and enforceable property rights to ensure they have an opportunity to obtain a return on their investments.

As our case studies report, there is no realistic substitute for private investment supported by the patent system to sustain the expert, professional ecosystem that brings treatments from bench to bedside.

Despite the importance of stable and reliable patents, Congress, the courts, and other institutions have imposed radical changes on the U.S. patent system over the past 15 years. It is undisputable that U.S. patents are harder to get, more likely to be invalidated, and much more expensive and difficult to enforce.

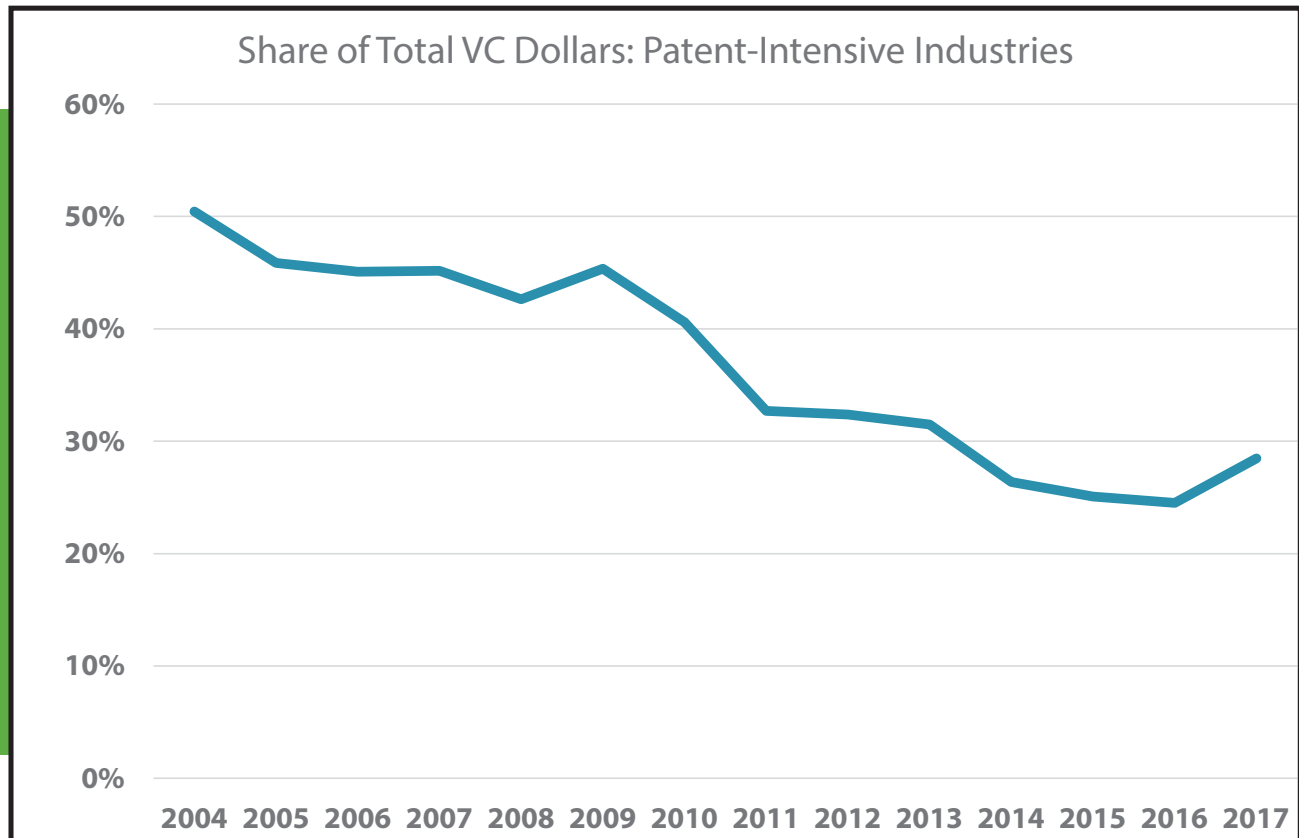
As these changes have occurred, innovators and investors warned that it would be harder to justify investments and to build new businesses in the fields that relied most on patents, such as the life sciences. That has proven to be the case, although a growing economy obscured some of the harm for a time.

Our report now establishes that investment has shifted out of patent-intensive industries, and innovators, managers, and investors say it is happening to a large degree because of changes to the patent system.

We obtained data on venture capital investment in the U.S. from 2004 to 2017 which shows clearly that venture capital investment decisively shifted away from patent-intensive industries.



Figure 1: Share of Total VC Dollars Patent-Intensive



* Definition of patent-intensive industry used is from USPTO's report on Intellectual Property and the U.S. Economy: 2016 Update.

In 2004, the majority of VC investment went to the patent-intensive manufacturing industries as they are defined by the U.S. Patent and Trademark Office. By 2017, the share of funding received by these patent-intensive industries dropped from over 50% in 2004 to about 28% in 2017 (after reaching a low of 24.5% in 2016). The trend is illustrated by *Figure 1: Share of Total VC Dollars Patent-Intensive Manufacturing Industries* shown above.

One graph tells much of the story. In 2004, patent-intensive industries claimed the majority of venture capital funding, attracting more venture capital than industries that relied less on patents. Since then, the sectors experienced a dramatic reversal in fortune, with the non-patent intensive industries attracting over 70% of venture capital since 2013. (See graph on next page.)

What venture capitalists invest in matters because it determines the future shape of our economy. Tomorrow's leading companies, innovative medical treatments, and new products are most likely to arise from companies that start out with venture capital backing. With less investment in patent-intensive industries, society will likely enjoy less of the things those businesses produce: lifesaving and game changing innovations and U.S. technological leadership.

Our interviews with innovators, investors, and executives at leading institutions explained the reasons behind these trends. For all of these successful, driven, and innovative individuals, patents were essential to their ability to innovate and invest.

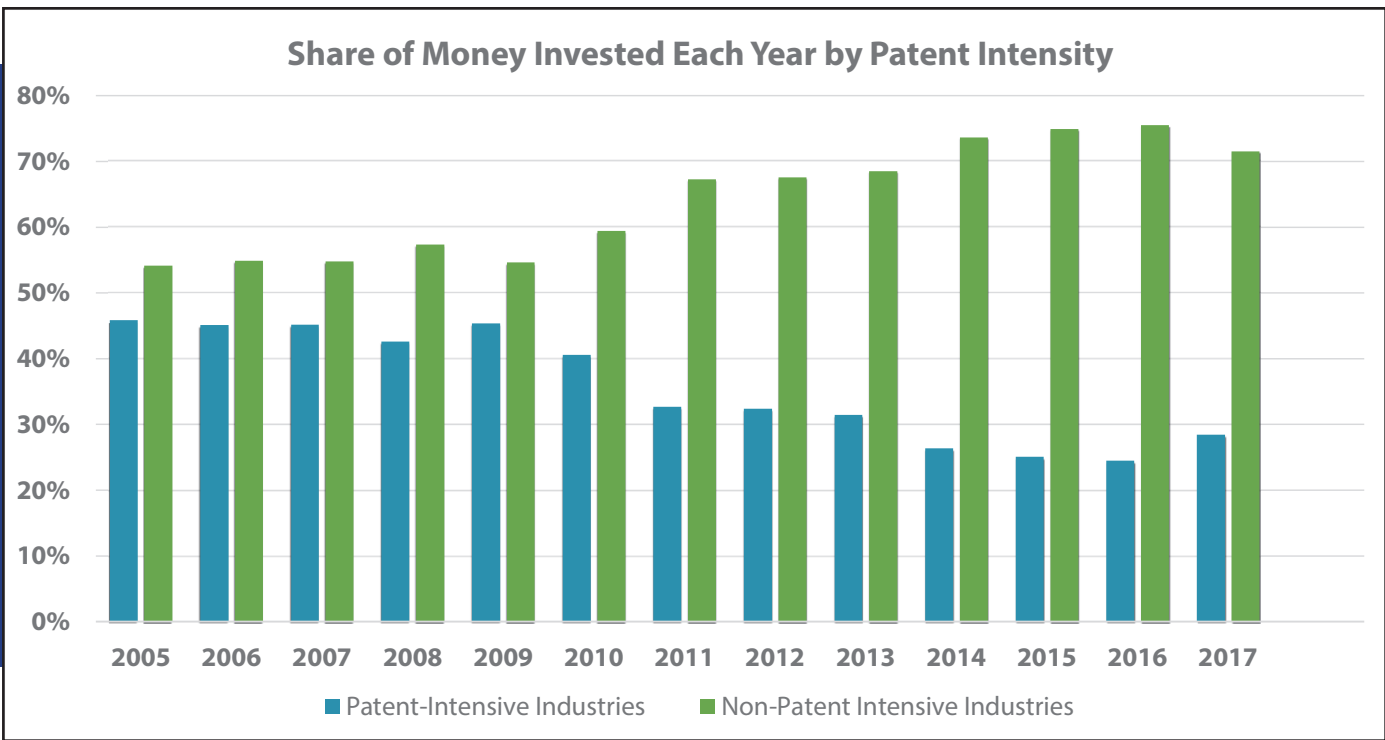
As Dr. Derrick Rossi, a leading biomedical researcher and biotech startup founder described it, developing innovative medical treatments “costs of hundreds of millions and is a 10-year road. That’s a lot of investment. If you could not protect it at the end of the day, you would not have an industry. There has to be the promise of protection and the ability to market it. Losing the ability to patent would be the end of this industry.”

Some expressed frustration and disappointment with how changes to the patent system have changed their focus. For example, Josh Makower of New Enterprise Associates and Eb Bright of ExploraMed have a long, successful track record of working together launching products and investing in the medical device field.

Makower and Bright have moved their investments from economically riskier implants that address serious medical needs to a greater focus on quality of life products. Bright regrets the “disease conditions that are not being researched ... while quality of life is important, we are less likely to address issues such as cardiovascular disease and chronic diseases such as diabetes and kidney conditions.”

Cleveland Clinic, one of the world’s leading medical research institutions, recently had several fundamental patents invalidated for an important diagnostic test for cardiovascular health. In U.S. Senate testimony, Peter O’Neill, Executive Director of Cleveland Clinic Innovations, explained the impact, saying that “financial supporters are following federal court cases like ours, and weighing whether a patent is likely to withstand a court challenge.”

One of O’Neill’s colleagues, Mary Kander, a manager at Cleveland Clinic Innovations is concerned that investors are becoming wary of diagnostic tests. She said that “personalized medicine is based on being able to determine the presence of biomarkers in a patient. That’s the future — being able to determine which drugs to use and the dosage to administer based on a patient’s individual characteristics. The unavailability of diagnostic patents, or uncertainty regarding their validity, is likely to affect an important component of personalized medicine.”



Recently, many policymakers have begun to see that changes to the patent system have gone too far. There are now several pending legislative proposals to restore predictability to the patent system. Such proposals have included curtailing abuses of the post grant proceedings, clarifying and restoring patent eligibility to diagnostics and other key technologies, and restoring the presumption of the right to injunctive relief in situations where a patent has been held valid and infringed. It is also worth noting that under the leadership of Director Andrei Iancu, the USPTO has demonstrated much stronger

support for the role of patents in the U.S. economy and made several policy changes that have strengthened the ability of inventors to protect their patents. Director Iancu has also supported the need to clarify patent eligibility for key technology sectors. Both the data and the words of innovators and investors presented in this report make the case for such changes. Society needs its most successful people working on its most compelling problems. The patent system should support such work.

Key Findings

- While venture capital funding grew during the recent economic expansion, the share of money invested in patent-intensive startups that develop critical technologies such as medical devices and supplies and pharmaceuticals and biotechnology declined.
- Less patent-intensive sectors such as social networking, consumer finance, food and beverage, and restaurants, hotels and leisure attracted a significantly larger share of venture capital in recent years.
- The share of venture capital funding received by the most patent-intensive businesses dropped from over 50% in 2004 to about 28% in 2017.
- The data show a precipitous decline in the relative share of funding going to companies developing products in the pharmaceutical and biotech sectors. Overall, the sector experienced a 20% decline in share of funding.
- VC investment in pharmaceuticals went from a 7% share of all investments in 2004 to a 0.79% share in 2017. In 2008, the share of all VC funding going to medical devices was nearly 12% of all VC funding. By 2015, the share halved, dropping to less than 6%, where it remains.
- The share of funding for businesses developing patent-intensive high-tech hardware, such as computer hardware and semiconductors, has dropped significantly.
- In fact, startup companies creating semiconductors now receive less funding in both relative and absolute terms, as they received not just a smaller share of funding but about \$1 billion less in funding from 2013–2017 than they did from 2004–2008.
- Interviews with leading inventors and investors indicate that changes to the patent system are causing VC investment to flow away from key life sciences investments. As one said, “we are less likely to address issues such as cardiovascular disease and chronic diseases such as diabetes and kidney conditions... These high-impact types of diseases are not being addressed like they would have been previously.

About USIJ

The Alliance of U.S. Startups & Inventors for Jobs (USIJ) is a group of inventors, startup companies, venture capitalists, incubators, and research institutions who have come together in the interest of safeguarding our nation's innovation ecosystem. The research and development that our companies and institutions perform has led to numerous breakthrough technologies in fields such as medical devices, mobile technologies, biotechnology, clean energy, and cloud computing. Our venture capital members and incubators have — for many years — founded and financed dozens of companies that have generated billions of dollars in value and created millions of jobs.

Our Mission

We invent real things and create real companies, and we support efforts to strengthen the patent system in the United States. A strong patent system is integral to our nation's innovation ecosystem and global competitiveness. We are committed to promoting a strong intellectual property system that supports innovation, investment, and breakthrough technologies that change our world. Our mission is to ensure this system continues to thrive for the benefit of American startups and inventors, and most importantly, American jobs.



Mark F. Schultz

About the Author

Professor Mark F. Schultz is the Goodyear Tire & Rubber Company Endowed Chair in Intellectual Property Law and the Director of the Intellectual Property and Technology Law Program at the University of Akron School of Law. He teaches and writes primarily in the area of intellectual property. Prior to coming to Akron, he was a professor at Southern Illinois University School of Law for 16 years and was co-founder and a leader of the Center for Protection of Intellectual Property (CPIP) at George Mason University in Washington, DC, where he remains a non-resident Senior Scholar. He also serves as a Senior Fellow of the Geneva Network, a UK-based think tank focused on international IP, trade, and public health.

Professor Schultz graduated with honors from The George Washington University School of Law. He served as a judicial clerk for the United States Court of Appeals for the Federal Circuit and the United States Court of Federal Claims. Prior to joining academia, he practiced law for a decade, serving as outside general counsel to several tech startups and helping technology companies to expand their businesses and commercialize their intellectual property in dozens of countries.



1800 M Street, NW
Suite 500, South Tower
Washington, DC 20036
www.usij.org | 202-327-8100

Contact: Chris Israel
USIJ Executive Director
Israel@acg-consultants.com



ALLIANCE FOR U.S. STARTUPS & INVENTORS FOR JOBS