

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



POLICY REPORT

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

Written by Mark F. Schultz

July 2020

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. USIJ is 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.



Table of Contents

Key Findings	4
Executive Summary.....	5
Part I. An Introduction	9
Part II. The Changing Climate for U.S. Investment and Innovation in Patent-Intensive Industries.....	13
Changes to the Patent System since 2007	13
What We Know So Far about Investment Trends in Patent-Intensive Industries	15
Conversations with Innovators and Investors	17
Part III. Trends in U.S. Venture Capital Investment 2004–2017	24
Investment in Patent-Intensive Manufacturing Industries.....	25
Broad Industry Sector Trends in VC Investment.....	28
Analysis of Selected Industries Winning and Losing Share of VC Funding	31
Year-to-year Trends 2004-2017.....	34
Part IV. Case Studies: Innovators and Investors in Patent-Intensive Industries	38
Eb Bright: ExploraMed	38
Josh Makower: ExploraMed & New Enterprise Associates.....	41
Derrick Rossi: Moderna, Magenta, Intellia, and Convelo Therapeutics.....	44
Barney Cassidy: Juno Therapeutics	48
Cleveland Clinic, Diagnostic Tools.....	50
Mary Kander	51
Bibliography.....	53
Appendix: Methodology	54
About the Author	59

EXECUTIVE SUMMARY

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 has 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. Everybody is less well off.”

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 were borne 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.

This paper reports 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.

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.

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.

¹ Goodyear 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.

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.

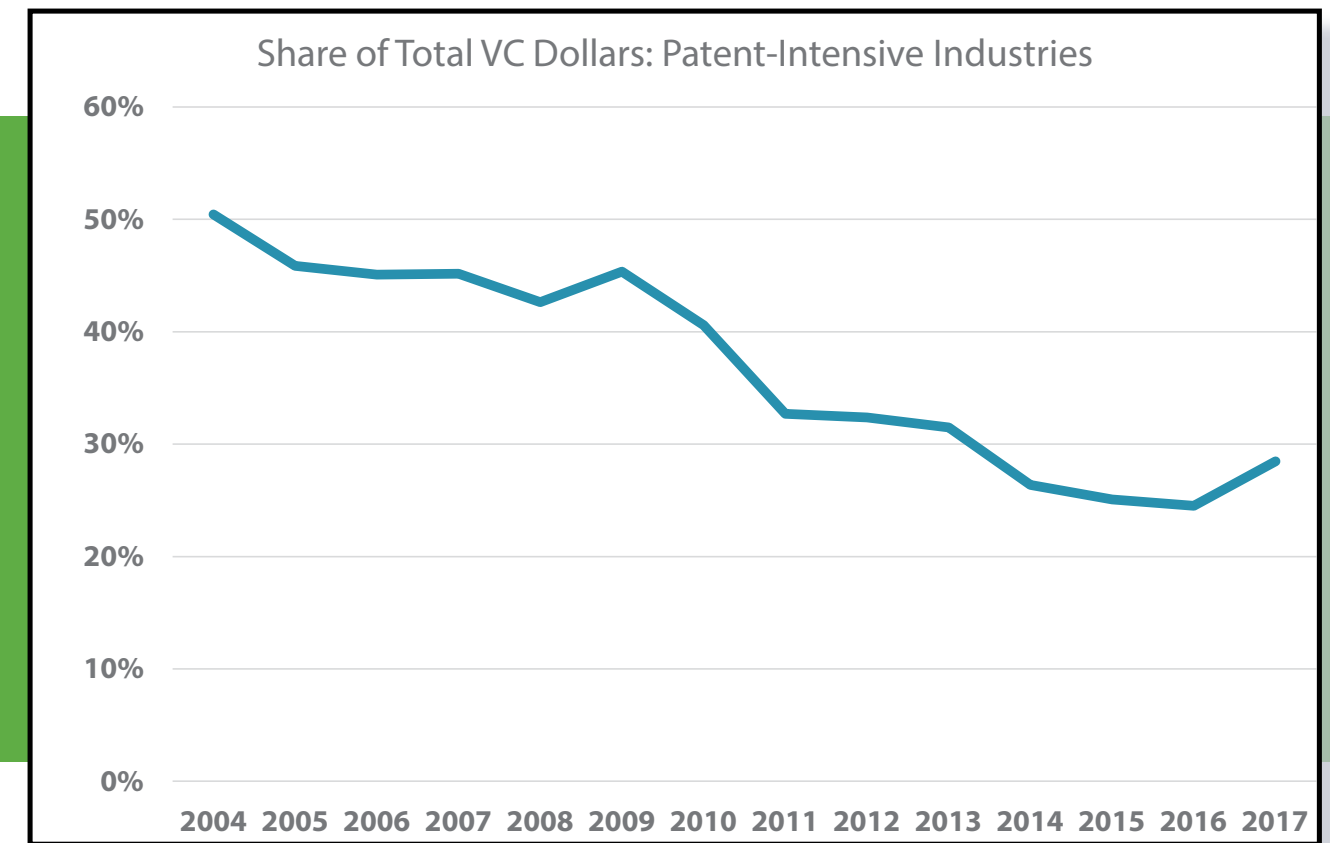
We obtained data on venture capital investment in the U.S. from 2004 to 2017 which shows clearly that venture capital investment decisively shifted away from patent-intensive industries.

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 on next page.

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 page 8.)

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

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.

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."

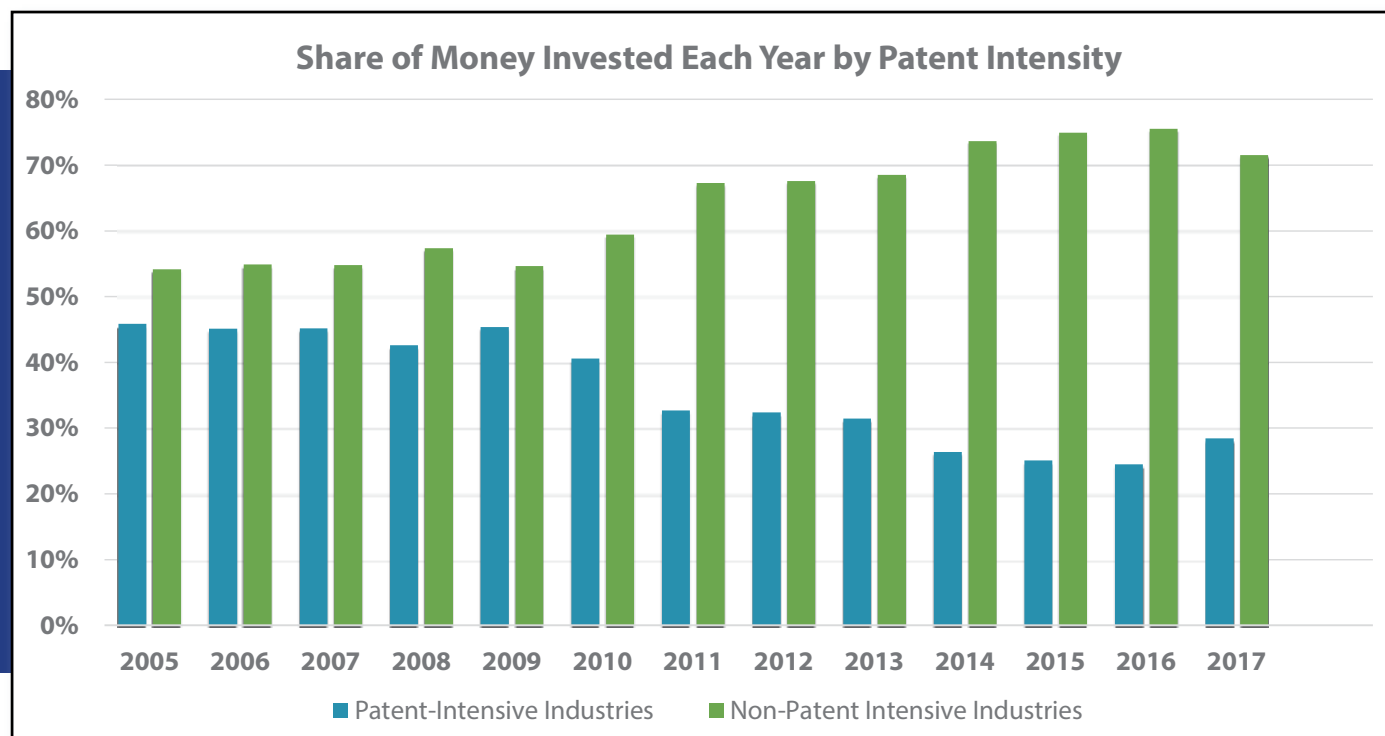
One of O'Neill's colleagues, Mary Kander, a manager at Cleveland Clinic Innovations is concerned that investors are becoming wary of diagnostic tests. She said that "personalized medicine is based on being able to determine the presence of biomarkers in a patient. That's the future — being able to determine 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.

Figure 2: Share of Money Invested Each Year by Patent Intensity



Part I: An Introduction

The U.S. patent system has changed dramatically over the past two decades. Congress, the courts, and the U.S. Patent and Trademark Office have made it harder to get, keep, and enforce patents. The courts have narrowed patentable subject matter and made it harder to stop infringers. Congress and the USPTO have increased opportunities to invalidate patents and made it easier to do so. While the USPTO has recently made improvements in an attempt to rebalance this situation, overall these changes have tipped the scales against smaller businesses, making it too expensive for many to enforce their patents.

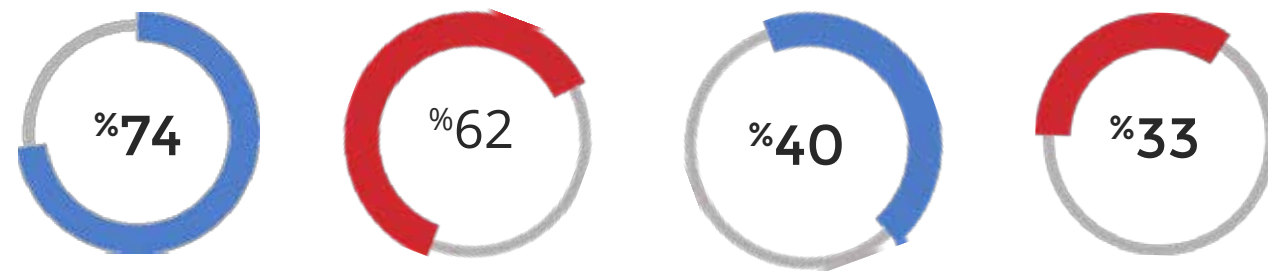
The wisdom of these changes has been much debated. Proponents of stronger, more effective patents contend that the cumulative effect of the changes has harmed innovation and investment by making patents less useful, dependable, and predictable. Critics of the patent system have pushed for and welcomed the changes, contending that the patent system had become too strong, to the point that it was counterproductive to innovation.

Whatever one's position regarding recent changes to the patent system, one ought to expect that making significant changes to the patent system would have significant effects on investment in innovative activities. People consistently say that patents matter, and they back their words with actions and large sums of money. Innovators and investors frequently cite the importance of patents to developing new technologies, starting businesses, and securing investment. A number of surveys support these contentions, showing that businesses value them strategically and that investors rely on them. Nevertheless, some do contend that patents interfere with their work or are less relevant in some fields – but not that they do not matter. Individual inventors, businesses, and others collectively spend billions of dollars to obtain and enforce patents, to challenge their validity, and to lobby for changes in the system.

The serious discussion, therefore, is not whether, but rather how, and by how much, investment and innovative activity have been affected by changes to the patent system. By now, enough changes to the system have accumulated and enough time has passed that effects have started to show. It is challenging, however, to determine cause and effect in such a dynamic, changing field as investment in innovation, which is highly responsive to changing technology, shifts in the market, and economic conditions. Data for private investments are also hard to obtain, change is constant, and it is difficult to pinpoint any one cause for shifting investment patterns.

The difficulty of documenting changes in investment and innovation, and the even greater difficulty of pinpointing their causes, allows for competing narratives. Critics of the changes we discuss to the patent system have predicted that investment would move away from patent-intensive sectors such as the life sciences. Many of these critics were investors and entrepreneurs who based their views on first-hand experience. Proponents of such changes have responded by pointing out that venture capital investments have continued to increase overall, and that new companies and business models continue to emerge.

However, evidence has begun to accumulate that confirms the concerns of critics. One of the key contributions has been a study by Professor David Taylor of SMU School of Law, which surveyed investors to determine how recent patent eligibility cases have changed the behavior of venture capital and private equity investment firms. Professor Taylor surveyed 475 venture capital and private equity investors to study the impact of the Supreme Court's eligibility cases on investment decisions. Findings included:



Source: Taylor 2020

- **74% said that patent eligibility is an important consideration in firm decisions whether to invest in a company**
- **62% said that their firms were less likely to invest in a company developing technology if patent eligibility makes patents unavailable**
- **40% of the investors who knew about at least one of the Court's eligibility cases said they had somewhat negative or very negative effects on their firm's existing investments**
- **about 33% of the investors who knew about at least one of the Court's eligibility cases said they affected investment decisions by decreasing investment and particularly by shifting away from investments in biotechnology, medical devices, and pharmaceuticals**

This report supplements these previous findings with two important contributions to the discussion:

First, we document that the focus of venture capital investment has indeed changed. We obtained data on venture capital investment in the U.S. from 2004 and 2017. The data comes from Pitchbook, a comprehensive database of US venture capital deals,

THERE ARE SOME IMPORTANT INVESTMENTS AND INNOVATION THAT WILL NOT HAPPEN, AND ARE NOT HAPPENING, WITHOUT AN EFFECTIVE, RELIABLE, AND PREDICTABLE PATENT SYSTEM.

IN PARTICULAR, THERE IS LESS INVESTMENT GOING TO HIGH-IMPACT, LIFE-SAVING INNOVATIONS AND TO OTHER STRATEGICALLY CRITICAL TECHNOLOGIES.

which annually tracks the number of deals, companies receiving investments, and amounts of investment, broken out in detail by industry segment. This data provided an opportunity to examine trends in venture capital investment. In absolute terms, overall investment has grown along with the population and the economy, increasing roughly four-fold between 2004 and 2017, but the emphasis has shifted decidedly away from patent-intensive industries.

Second, we complemented and sought explanation for the trends we found by interviewing leading innovators, investors, and executives at leading institutions to understand the importance of patents and changes to the patent system to their work. Case studies such as this are helpful to provide insights to interpret and explain broader data, such as our investment trends data and Professor Taylor's survey results.

From all this evidence, a picture emerges: Investment no longer flows to patent-intensive industries as readily as it once did. Innovators are still doing important work and investors are still investing in these activities, but changes to the patent system have changed their priorities.

Some of the most dynamic and innovative people working in the U.S. economy have responded to incentives and moved their work and money away from patent-intensive industries. They are working and investing relatively less on pharmaceuticals, biotech, semiconductors, and manufacturing generally, sectors long seen as key to innovation. They are investing more in software and in expanding traditional industries such as food and clothing.

The innovators and investors with whom we talked are optimistic and driven, but pragmatic. None of them have given up. They still are innovating and investing in game-changing ideas. But, unsurprisingly, these brilliant and accomplished people focus their efforts not only where they will have the greatest impact, but also where their work and investments will not be frustrated and undermined by insecure property rights. There are some important investments and innovation that will not happen, and are not happening, without an effective, reliable, and predictable patent system. In particular, there is less investment going to high-impact, life-saving innovations and to other strategically critical technologies.



No single study can settle the question of the effect of a diminished system of patent protection on investment and innovation, but that does not mean the effects are unknowable. The patent system has changed, significantly. Venture capital investment has shifted away from patent-intensive industries. While everybody knows that correlation does not prove causation, this objection pales in light of the accumulated evidence. The trends we report here are consistent across different patent-intensive industries. Professor Taylor's survey data indicate an explanation. So do our case studies and numerous other qualitative reports.

In the end, the evidence points toward a fairly logical, predictable conclusion: Making patents less enforceable, less reliable, and harder to obtain has made investors relatively less likely to invest in patent-intensive industries.

With that evidence in hand, the stakes of the policy debate are clearer. Changes to the patent system have come with at least one clear cost: A shift away from investment in industries that rely on patents. Among those businesses receiving a smaller proportion of investment are startups in the life sciences that bring life-saving treatments from labs to patients. Whatever benefits are claimed from weakening patents have to be weighed against that cost.

CHANGES TO THE PATENT SYSTEM HAVE COME WITH AT LEAST ONE CLEAR COST: A SHIFT AWAY FROM INVESTMENT IN INDUSTRIES THAT RELY ON PATENTS. AMONG THOSE BUSINESSES RECEIVING A SMALLER PROPORTION OF INVESTMENT ARE STARTUPS IN THE LIFE SCIENCES THAT BRING LIFE-SAVING TREATMENTS FROM LABS TO PATIENTS.

Part II: The Changing Climate for U.S. Investment and Innovation in Patent-Intensive Industries

In the last 15 years, the U.S. patent system has undergone a great deal of change. Patents are now harder to obtain, harder to enforce, more likely to be challenged and invalidated, in some cases long after they have been granted. Viewed individually, certain of these changes were based on plausible justification, but the cumulative effect has been to make patents less reliable and predictable. Evidence has begun to accumulate that less predictable and reliable patents have deterred investment and work in industries that rely on patents.

This Section briefly surveys changes to the patent system and what we know so far about their effect.

Changes to the Patent System Since 2006

Since the early 2000s, the patent system has faced a growing volume of criticism and resulting efforts to change the system to make patents harder to get and enforce. While these critiques did not go unchallenged, patent critics have enjoyed many successes in the courts, Congress, and other key institutions in the patent system. As a result, the U.S. patent system today works quite differently from the one the U.S. had at the turn of this century.

Key changes include the following:

Injunctions are far harder to obtain. In 2006, the Supreme Court held in *eBay Inc. v. MercExchange*,² that courts should not presume that a patent owner is entitled to an injunction following a finding of patent infringement. Since then, lower courts have interpreted the decision in a way that has made injunctions much harder to obtain for many patent owners, particularly for companies that license technology rather than sell products.³

The U.S. adopted a first to file system. The 2011 America Invents Act switched the U.S. from a first-to-invent system to a first-to-file system. While this system eliminates uncertainty and disputes between parties regarding who the first true inventor is, it also tends to favor larger businesses with the resources to promptly file patents. It can be particularly problematic for life sciences researchers and startups because it forces them to file early, despite their long development timelines.

The America Invents Act created a post-grant opportunity to challenge the validity of patents. The AIA instituted post-grant proceedings that made it much easier to challenge patents.⁴ These proceedings allow any third party to challenge the validity of a patent in an administrative

² *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006).

³ Ryan T. Holte, *The Misinterpretation of eBay v. MercExchange and Why: An Analysis of the Case History, Precedent, and Parties*, 18 *Chapman Law Review* 677 (2015).

⁴ We refer to post-grant proceedings generally for the sake of simplicity, but the AIA created two separate administrative procedures for invalidating patents. The first is "Post-grant Review" or PGR, which is available only during the first nine months after issuance and can be based on any grounds available under the Patent Act. The second type is "Inter Partes Review" or IPR which can be brought anytime during the life of a patent but can be based only on lack of novelty or obviousness.

proceeding before the Patent Trial and Appeal Board, which is an administrative tribunal within the patent office. The intention was to create a lower-cost, faster way to review the validity of patents.

The IPR system resulted in many patents being struck down. In the initial years after IPRs became available in 2012, invalidation rates were extremely high, and the system included features that tilted strongly toward challengers. The situation has improved somewhat but remains challenging for patent owners. Most cases challenging PTAB constitutionality, procedures and outcomes have gone poorly for patent owners.

It has become much harder to get and keep patents in some fields; there is widespread uncertainty about what the rules are. The U.S. Supreme Court has narrowed patent eligibility in a series of cases starting in 2010. The first case was *Bilski* (2010),⁵ followed after a brief pause by the quick succession of *Mayo* (2012),⁶ *Myriad* (2013),⁷ and *Alice* (2014).⁸ These cases created new legal criteria for patent eligible subject matter under 35 USC 101. The new criteria have particularly impacted medical diagnostic, software, and gene patents, but their impact has been much broader than that.

Much has been said and written elsewhere about these cases, so we will sum a few salient points briefly:

- The current legal tests for patent eligibility have excluded many inventions that likely would have been patentable before 2010, both in after-the-fact in lawsuits and post grant proceedings and during initial examination at the USPTO.
- The cases are widely criticized as creating uncertainty for inventors and investors. The legal tests are viewed as unworkable and confusing, as evidenced by the U.S. Court of Appeals for the Federal Circuit's 2019 denial of rehearing en banc in *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*, which included eight separate opinions, with no single opinion achieving more than four judges in support. One point on which these judges widely agree is that the Supreme Court or Congress needs to clarify standards, which both seem disinclined to do.

Further legislative changes have been frequently and seriously proposed. Many industries that rely on patents believed, or at least hoped, that the 2011 America Invents Act would end efforts to change the patent system. This hope was reasonable. It was the first major change to the patent system since the 1952 Patent Act and the product of many years of debate and compromise among stakeholders.

Instead, further calls for change quickly followed.

For example, the proposed 2013 Innovation Act, and related bills in 2014 and 2015, would have significantly changed patent litigation with the goal of making it harder and much less

effective for patent owners to bring lawsuits, particularly startups and the entrepreneur-inventors that created them. The proposed legislation created several additional requirements for bringing suits. In particular, it included a fee-shifting provision that would have made it mandatory for the court to require the loser to pay the legal costs and fees of the prevailing party, with a further requirement that the shareholders would be responsible in situations where a corporate patent owner was unable to cover such expenses.

The Innovation Act and other legislative proposals to change the patent system, while unsuccessful, garnered significant support in Congress. To some extent, the possibility of yet more change has contributed to uncertainty about the future of the patent system for which investors and others likely have to account to some degree.

These were not the only changes to the patent system. For example, the AIA also instituted many other new rules and procedures, and the Supreme Court has introduced other changes, including rules restricting the courts in which specific patent cases can be brought. The USPTO has also continued to adjust its examination guidelines and procedures.

In sum, the patent system has experienced tremendous changes in the last decade and a half and remains unsettled.

What we know so far about investment trends in patent-intensive industries

A number of studies and reports have found changes in reliance on and enforcement of patents since these changes to the U.S. patent system. For example, IAM's Annual Benchmarking Survey has reported for several years running that executives report patents have dropped in price since the year before. (IAM 2018). Similarly, according to Docket Navigator and Lex Machina, patent litigation filings have dropped significantly in recent years.⁹

Less reliance on patents matters in part because patents are important to high-tech startups and IP-intensive industries that create jobs. A USPTO study summed up the importance thus: "patenting firms represent only 1 percent of U.S. firms (2000–2011) but are among the largest in the economy, accounting for 33 percent of employment. Patenting firms create more jobs than their non-patenting counterparts of the same age across all age categories except the very youngest (firms <1 year old)."¹⁰

Patents are particularly important to startups. For example, in a forthcoming paper, researchers found that success in obtaining a US patent led to "55% higher employment growth and 80% higher sales growth five years later. Patent winners also pursue more, and higher quality, follow-on innovation. Winning a first patent boosts a startup's subsequent growth and innovation by facilitating access to funding from VCs, banks, and public investors." (Farre-Mensa et al 2019). Similarly, a recent EPO report found that patents in Europe benefit SMEs. For example, SMEs

⁵ *Bilski v. Kappos*, 561 U.S. 593 (2010).

⁶ *Mayo Collaborative Servs. v. Prometheus Labs*, 566 U.S. 66 (2012).

⁷ *Association for Molecular Pathology v. Myriad Genetics*, 569 U.S. 576 (2013).

⁸ *Alice Corp. v. CLS Bank International*, 573 U.S. 208 (2014).

⁹ Brian G. Arnold, Samantha Picans, & Ian R. Walsworth, *Patent Litigation Trends in The Wake of TC Heartland*, I.P. Address, April 25, 2019, <https://lewisbrisbois.com/blog/category/intellectual-property-technology/patent-litigation-trends-in-the-wake-of-tc-heartland>

¹⁰ USPTO, *Intellectual Property and the U.S. Economy 2016 Update* at 6.

that filed patents were “25% more likely to experience turnover growth of 10% or more during three consecutive years.” (EPO 2019).

Changes in law that weaken patents thus could be expected to divert at least some investment away from startups that depend on patents. Indeed, evidence indicates that although venture capital funding is still growing, it is shifting away from early stage companies and patent-intensive businesses to social media and later stage businesses. (ITIF 2018). The 2020 Silicon Valley Index, which measures economic performance in Silicon Valley and San Francisco, the U.S. startup capital, shows a similar shift away from investment in early stage companies. In the last 5 years there has been a 90% drop in the number of new startups in Silicon Valley and an 80% drop in the number of new startups in San Francisco, and angel investing hitting its lowest level since 2012. (Silicon Valley Institute 2020).

Prof. David Taylor’s work on this issue is particularly illuminating. Taylor surveyed 475 investment firms and found that they were aware that patentable subject matter had narrowed in the U.S., that it mattered to them, and that they had shifted investment from the biotechnology, medical device, and pharmaceutical industries as a result. (Taylor 2019).

Taylor showed that investors in some fields are more sensitive to the availability of patents. When asked how their investing would respond to the elimination of patents in a particular field, the overwhelming majority said they would decrease their investments in the biotechnology (77%), medical device (79%), and pharmaceutical industries (73%). By contrast, they said they would not stop investing in or only slightly decrease investing in the construction (89%), software and Internet (80%), transportation (84%), energy (79%), and computer and electronic hardware (72%) industries. Importantly, 33% of investors who were familiar with subject matter eligibility cases reported that these cases impacted their firms’ investment behavior, reporting that they shifted investments away from the biotechnology, medical device, and pharmaceutical industries.

Other data reinforces Taylor’s results. In late 2019, Piper Jaffray found that \$8.7 billion had flowed out of healthcare- or biotech-dedicated funds in 2019. A Piper Jaffray analyst called the money flowing away from these life sciences funds “seemingly the new normal.”¹¹

Why does it matter which industries attract venture capital? Some have observed that VC funding grew significantly during the recent expansion. This leads to the question whether the composition of VC investment matters.

Trends in venture capital investment are important because in recent decades, companies that started with venture capital backing come to dominate the U.S. economy, producing value and jobs. One study found that of all publicly-held companies, about 20% of market capitalization and 11% of employment was contributed by companies that were originally venture-backed. (Gornall & Strebulaev 2015). When one accounts for the fact that the VC industry is relatively young, these impressive numbers increase greatly. The study further examined only publicly-held companies founded since 1974, and found that they accounted for 63% of market capitalization and 38% of employment — more than 3,000,000 jobs from companies that typically start out as small enterprises.

Less investment today in startups in the life sciences, computer hardware, and semiconductors means that there will be fewer of those companies and products tomorrow than there could have been. It means fewer new treatments, less innovative medical equipment, and fewer of the high tech businesses that the US relies upon to maintain its worldwide leadership role in strategically important areas of science and technology.

The shift in investment away from patent-intensive industries thus has important implications for public policy, the U.S. economy, and individual Americans. While it is unlikely that there is a single cause for this shift, there is ample reason to believe that making patents less effective and reliable has much to do with it. We decided to investigate further by talking to leading innovators and investors.

Conversations with leading innovators and investors

For this project, we talked to several people who have had notable success in innovating, leading, and investing in patent-intensive fields to understand how the patent system affects their work. We wanted to find out just how important patents were to success in their fields and whether and how changes to the patent system have impacted them.

We sum up our findings from these interviews here in this Section, and provide the in-depth case studies in Section IV.

Our case study interviews were with:

- **Eb Bright, an innovator, entrepreneur, and executive in the medical device field as well as the CEO of a medical device incubator.**
- **Barney Cassidy, a former executive in a biotech company that successfully went public and was later acquired**
- **Mary Kander, a manager in the commercialization and licensing arm of a leading medical research institution**
- **Josh Makower, a venture capitalist as well as an innovator, entrepreneur, and executive in the medical device field**
- **Dr. Derrick Rossi, a researcher, entrepreneur, and executive in the biotech field**

The Fundamental Importance of Patents at Every Stage

One universal belief expressed by the interviewees was that patents are fundamental and essential to the health of the life sciences sector. Concededly, this statement may seem unsurprising given that these subjects all worked in fields generally agreed to be patent-intensive. What was notable, however, was that these individuals viewed their fields from many different perspectives. Whether they were an early stage researcher, an entrepreneur, a tech transfer manager, or a public company executive, they all were adamant that reliable and effective patent protection was essential to the success of their work.

¹¹ Josh Nathan-Kazis, *Biotech Funds Are Beating the Market, but Investors Are Still Bailing Out*, NASDAQ.com, Nov. 8, 2019, available at <https://www.nasdaq.com/articles/biotech-funds-are-beating-the-market-but-investors-are-still-bailing-out-2019-11-08>.

“ EACH OF THESE STEPS TOOK TIME AND RESOURCES THAT WERE MADE POSSIBLE ONLY BY THE PROMISE OF RETURN ON INVESTMENT ENABLED BY PATENT PROTECTIONS. ”

Peter O'Neill, Executive Director of Cleveland Clinic Innovations, summed up the pervasive importance of patents at every step of bringing an innovation from early stage research to a solution for



Testifying before the Senate Judiciary Committee in 2019, Peter O'Neill, Executive Director of Cleveland Clinic Innovations, summed up the pervasive importance of patents at every step of bringing an innovation from early stage research to a solution for patients and consumers. "Each of these steps took time and resources that were made possible only by the promise of return on investment enabled by patent protections."

Thus, patents are fundamental and essential to key participants in the system at every stage:

- For innovators deciding what problems to work on and how to address those problems;
- For entrepreneurs building companies;
- For startups and established companies choosing which products to develop and commercialize; and
- For venture capitalists deciding whether or not to invest.

For entrepreneurs who develop applied solutions for patients and consumers, patents shape the work they do from the very start. In the medical device field, Josh Makower said that "IP protection is absolutely essential... We will not do a project without it. These projects take so long, that you can't do it without this protection."

In other fields such as biotech where basic research occurs without necessarily focusing on commercialization, patents make the difference between interesting research that stays in the lab and practical solutions that reach patients. As Dr. Derrick Rossi said, "you can be working on the coolest thing, but investors need to know that there is some protection for their investment, plain and simple." IP is "the future prospect that reassures investors."

From a research institution's point of view, deciding whether to attempt to commercialize research starts with an assessment of viability, which is one of the top considerations for most products. As Mary Kander said, her team is unlikely to move forward in most fields without a patent because "investors are not going to fund a project where there are not patents."

The perspective of an executive from a later-stage company explains why patents are needed to move forward from basic research into commercialization. According to Barney Cassidy, "the heart of the company was the IP that enabled us to develop the drugs we did." "It's

unquestionable that it was absolutely imperative that we have strong patent protection. It took in the neighborhood of \$2.5 billion to develop this therapy, and we needed to secure that investment with patents."

Indeed, the need to secure patents was repeatedly cited as both a necessity to attract investors and a duty to protect the interests of those investors. As Eb Bright put it, "we are using the money of limited partners, who are often retirement funds... The retirement plan's investors trust it to pick a venture capitalist who will make good choices. Part of making good choices is ensuring that investments can be protected by effective intellectual property rights."

For venture capital investment, Makower says that "It's a relatively binary check. The IP needs to be there, and the product needs to be non-infringing."

It's not necessarily just a single, early stage patent that's enough either. Executives of both startups and larger companies are mindful of the need to develop a quality portfolio of patents to secure investment. As Dr. Rossi observed, in his work as a startup CEO, he wanted a robust portfolio of patent filings before engaging with pharmaceutical companies. It was not only to protect the company's work prior to talking to potential investors, "but also to assure pharma that we had protectable assets. I put a massive push on this from day one."

For a larger company, a strong portfolio helps to justify and defend large investments in developing a product. Cassidy said "investors are very cautious about investing, unless there is a very strong set of patent assets held by the company. As General Counsel that was my focus." According to Cassidy, this focus included "patrolling the perimeter" of the company's IP rights, and "working out license agreements" where needed to strengthen that perimeter.

The subjects of our cases studies are not alone in their views of the importance of the patent system. For example, Robert Nelsen, of ARCH Venture Partners, and widely regarded as one of the leading VCs in the biotech field, expressed this unequivocal sentiment in a Forbes editorial: "Let us be clear: investments in the biotech industry are based entirely on patents. Without strong patents, we cannot raise money to find cures for disease."¹²

¹² Robert Nelsen and Hans Bishop, *New Patent Law Would Trash Disease Cure*, Forbes.com, March 24, 2015, <https://www.forbes.com/sites/matthewherper/2015/03/24/new-patent-law-would-trash-disease-cures/#6ad8657524d5>

The Impact of Changes to the Patent System

All of our interviewees were aware of changes to the patent system, but not all were equally impacted. Many saw significant changes in priorities and greater challenges.

For Bright and Makower, they saw the effect in the need to pass on very promising, important treatments. “It’s a shame,” Bright says citing one key example, “as I would love to work on bioelectronic medicine. We could do things to address inflammatory conditions without drugs. However, it’s still early days, and the science is uncertain. In the best of circumstances, that makes it hard to attract capital. Add the uncertainty about patentability, and we have decided not to pursue these inventions at this time.”

Similarly, Makower thinks that one of his early successes, TransVascular, which improved delivery of treatments to the vascular system, might not be possible today. Such small, but important changes are harder to patent.

“If there is a way to get it, we get it, but we do worry about whether claims are allowable.” In his view, “rigor in patenting is not bad, but things have become a little too hard.”

Makower also sees incumbents using post-grant proceedings to thwart disruptive startups, which makes them a riskier and less likely choice for investors. “It’s a much more vicious world for small entities with smaller bankrolls. It squashes innovation.” A small company like TransVascular might not survive. “Stepping into a space with large incumbents could mire a small company in patent litigation.”

Indeed, Makower and Bright say two of their portfolio companies that were once promising are not likely to make it due to changes in the patent system.

Kander says that potential licensees, and their investment partners, have become more skeptical of diagnostic tests because of Supreme Court rulings on diagnostics. “There is a wariness in terms of licensing biomarkers for commercial opportunities.”

“HOWEVER, IT’S STILL EARLY DAYS, AND THE SCIENCE IS UNCERTAIN. IN THE BEST OF CIRCUMSTANCES, THAT MAKES IT HARD TO ATTRACT CAPITAL. ADD THE UNCERTAINTY ABOUT PATENTABILITY, AND WE HAVE DECIDED NOT TO PURSUE THESE INVENTIONS AT THIS TIME.”

- Eb Bright, ExploraMed co-founder and serves on USIJ’s Advisory Committee

“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.”

- Mary Kander, General Manager of Technology and Commercialization for Cleveland Clinic Innovations

Licensees are much slower to license. “In the past, we could get interest from potential licensees once we filed a patent application and they could look at claims. Now it’s more typical that they want to wait to see if the patent issues.” This is “slowing the route to commercialization, as companies are more wary of licensing an unissued patent. Some will still do it, but it is much less frequent.”

Research continues, but it is impacting the ability to license, and without licensing, commercialization is less likely. She expresses concern about the impact: “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.”

Cassidy observes that changes to the patent system “have made it more difficult to obtain investment in early stage companies that have potential to bring disruption to the status quo. ... Many VCs decline to invest as broadly in early stage companies as they once did. Instead, they prefer to invest in later stage companies that have less exposure to patent challenges as an existential event.”

Cassidy observes that patent challenges for early stage companies drain precious investment dollars. A company facing a series of IPRs, for example, “faces a choice of funding litigation or innovation. There is a more direct tradeoff for early stage companies.”

Makower says this risk is hurting in the life sciences sector pervasively. “It makes every deal riskier, which has to be factored into every decision, from development, to investment, to evaluation, to exit.”

The sentiments of our case study participants were also expressed by innovators and investors from a variety of industry sectors. For example, Dr. Greg Raleigh, who holds a PhD. in electrical engineering from Stanford and is seasoned entrepreneur who invented much of the core technology that today’s wireless devices rely on testified at an FTC hearing in 2018 that changes to the U.S. patent system “destroyed” incentives for many innovators. In particular, he said that the IPR system had made it “too expensive” and “time consuming” for small companies to defend patents. Dr. Raleigh, who now serves as an advisor to startups at

“DEVELOPING A DRUG “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.”

- Dr. Derrick J. Rossi, CEO of Convelo Therapeutics

New Enterprise Associates added that, “we are now in a regime where we have influenced where we are making investments. Big inventions that require patent protections are far harder to justify an investment in today.” And, as Dr. Raleigh added, in complex technologies such as life sciences and 5G these investments are quite significant and rely on patient VCs, “today’s inventors typically need to invest between \$100 to \$300 million and spend 7 to 10 years to develop an invention to profitability — levels that require an outcome of \$500 million to \$1 billion to make sense.” In a world where it is nearly impossible to gain injunctive relief to protect a patent and damage awards don’t match the impact caused by infringement, these investment risks are extremely hard to justify.

Innovation without Patents?

We asked interviewees a speculative question, observing that some critics of the patent system hope to replace its role to some degree with more government funding, prizes and other mechanisms. We asked them, for example, whether new effective treatments could get to patients without the patent-driven commercial system we have now.

Dr. Rossi replied: “Not a chance. Academics are good at academia and fundamental science. They are not good at developing drugs for patients.”

The government would not manage the process well, according to Rossi. “This industry of professionals is out there... The more people that are involved in the chain, post-academic discovery, the more you have pros involved — all the way from IP filings to VCs to due diligence to assembling a team,” the more likely you are to develop a viable treatment.

According to Rossi, developing new treatments requires speed and agility. “This is why biotech startups are the predominant way to develop new treatments. They are nimble, follow the data, make quick decisions, and focus on the problem without distraction.”

Developing a drug “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.”

Cassidy observed that “Government has an important function in our society, but it is not equipped to make these decisions. Democratic decision-making is driven by passion, not by science, which is what should drive these decisions. The private investor has something to lose if he or she guesses wrongly.”

Kander notes that governments also look to patents to determine the viability of investments in innovation: “we get funding from the state of Ohio to help support some of our spinoffs, but even the state wants to see a patent first too. Everybody wants the certainty of a patent before they put their money at risk.”

The Work Continues, but It’s Different

For much of the period during which the U.S. patent system has been changed and weakened, the U.S. economy enjoyed an economic recovery and a long expansion. Venture capital investment has continued and increased. This has led some to argue, at least before the onset of the Covid-19 pandemic, that changes to the patent system have not harmed innovation and economic growth.

Nevertheless, as our data shows and other research such as Prof. Taylor’s survey indicate, investment has shifted away from patent-intensive industries. A natural consequence of this shift is that fewer resources are being invested in high job growth industries and socially important innovations.

How is growth continuing in light of these shifts, and what are their consequences? The answers can be found in the resilience displayed by our case study subjects and the warnings they provide regarding shifting priorities in investment.

One remarkable characteristic these individuals have in common is their optimism and drive to make a difference in the world. Making patents less secure has made their work harder, but they do not quit. They have, however, changed their behavior. Changing the patent system has changed the nature of their work.

Bright and Makower have shifted their innovation and investment away from medical devices that require expensive and lengthy development, such as implants, and to consumer devices. Thus, instead of implants to treat vascular problems or joint deterioration, they are producing devices that are faster to develop and cheaper to sell such as wearable breast pumps.

Kander is similarly concerned for the future of personalized medicine. The inability to patent diagnostics “is not impacting research, but it is impacting the ability to license.” This concerns her, as “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.”

While Bright praises the improvement in quality of life his latest innovations produce, he expresses regret at 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.”

“These high-impact types of diseases are not being addressed like they would have been previously,” says Bright. “Everybody is less well off.”

Makower agrees, saying “neither the healthcare system nor available treatments are ideal. We all experience pain and suffering that does not need to exist. If innovators can reduce health care costs, more people get treated. If innovators can develop better treatments, more people get healthier. Fundamentally, all these changes to the patent system affect our health and quality of life.”

Makower also sees economic harm: “Weakening the patent system takes away jobs. It hurts America’s position within the global economy... If this continues, America will become a country of large, monolithic, slow, and not very innovative companies. That’s not what the American dream is about.”

These accounts from innovators were confirmed by what may be this report’s greatest contribution: our review of data regarding venture capital investment trends since 2004.

Part III: Trends in U.S. venture capital Investment 2004–2017

We examined data reporting US venture capital deals from 2004 through 2017 to determine whether venture capital investment in patent-intensive industries has changed during the time period in which the U.S. patent system has faced tremendous change. Professor Taylor’s survey results along with other reports lead us to expect that we would find that investment has shifted away from patent-intensive industries. That is indeed the case.

We found that the share of investment in patent-intensive industries dropped significantly from 2004 to 2017. **Overall, startups in patent-intensive industries in 2017 represented a significantly smaller share of all companies receiving VC funding, and they captured a smaller proportion of total VC funding, than they did in 2004. The trends have generally been downward.**

The data was obtained from Pitchbook, which attempts to document all venture capital deals that are reported in publicly available sources such as websites, news reports, regulatory filings, and press releases, and also through individual communication,¹³ For each year it reports, broken down by industry, the number of companies financed, the number of deals, and the total dollar amount. We calculated the proportion of all money or deals going to a particular industry, rather than absolute numbers, to normalize for economic growth. Appendix 1 explains our methodology in greater detail.

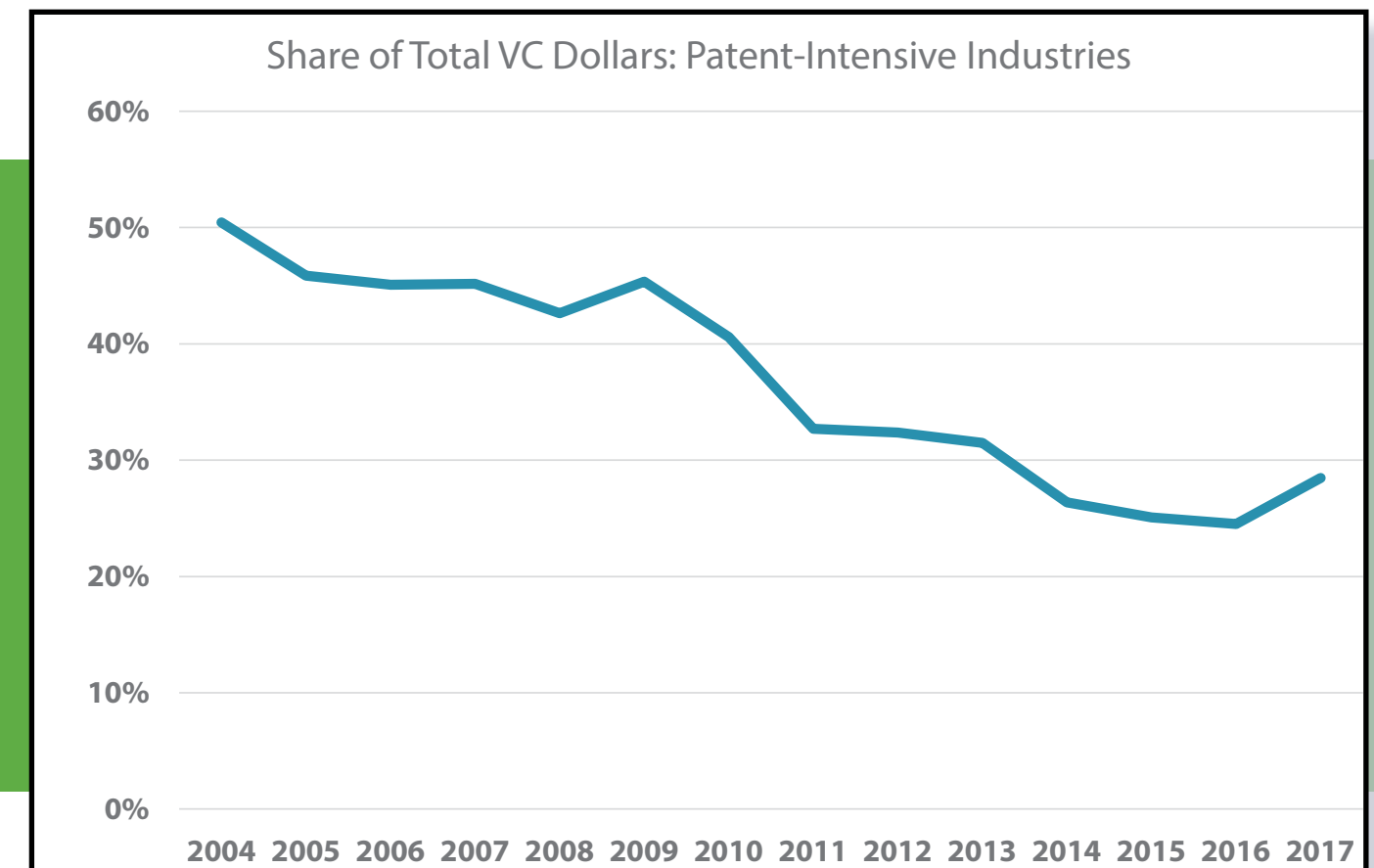
Our results were consistent using more than one definition of “patent-intensive.” There is more than one way to determine whether an industry can be considered patent intensive. One widely-

used definition follows the USPTO’s designation of industries as “patent-intensive” in its 2016 report on the contribution of IP to the US economy.¹⁴ In reality, however, the USPTO chose to apply that designation only to manufacturing industries, measured in terms of the “ratio of total patents over the five years (2009–2013) in a NAICS category to the average payroll employment by industry.”¹⁵ A patent-intensive (manufacturing) designation indicates that an industry is at or above the mean for manufacturing industries. In the next subsection, we examine investment in these patent-intensive manufacturing industries. Later, we examine other sectors of the economy.

Investment in Patent-Intensive Manufacturing Industries

The share of all VC funding going to patent-intensive manufacturing industries has dropped dramatically. In 2004, slightly more money went to the patent-intensive manufacturing industries (just over 50%) than the rest of the economy. By 2017, the share of funding received by the 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 has been fairly consistently downward, during this period, reaching a low of 24.5% in 2016, as illustrated by Figure 1.

Figure 3: Share of Total VC Dollars Patent-Intensive in Industries



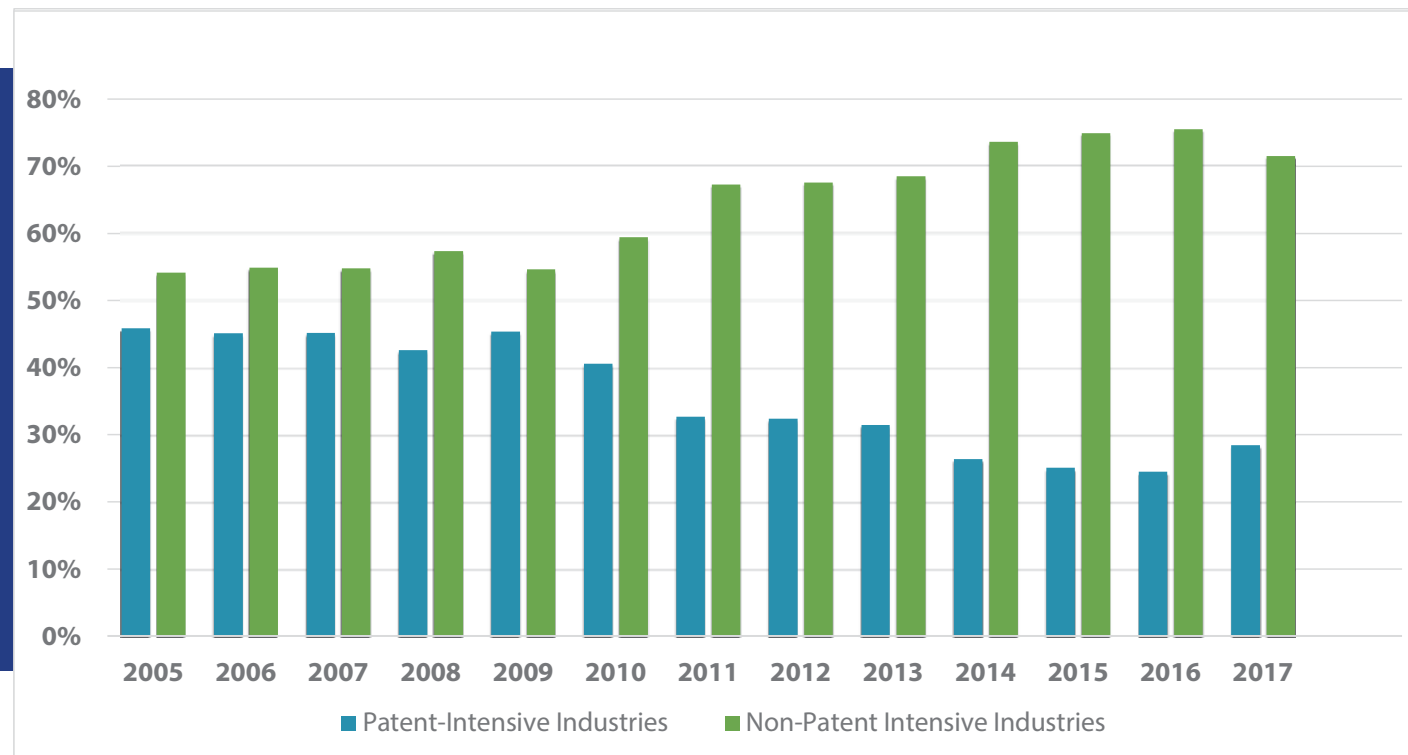
* Definition of patent-intensive industry used is from USPTO’s report on Intellectual Property and the U.S. Economy: 2016 Update.

¹³ Pitchbook, Research Process. <https://pitchbook.com/research-process>.

¹⁴ USPTO, Intellectual Property and the U.S. Economy (2012).

¹⁵ Ibid at 32.

Figure 4: Share of Money Invested Each Year by Patent Intensity



The sectors represented in these statistics are manufacturing industries with a ratio of patents-per worker at or above the mean, based on USPTO calculations. According to the USPTO, these are the patent-intensive industries, listed by NAICS code.

NAICS Code	Industry Title
3341	Computer and peripheral equipment
3342	Communications equipment
3343, -6	Other computer and electronic products
3345	Navigational, measuring, electromedical, and control Instruments
3344	Semiconductors and other electronic components
3251	Basic chemicals
3399	Other miscellaneous
335	Electrical equipment, appliances, and components
3391	Medical equipment and supplies
3254	Pharmaceutical and medicines
3253, -5, -6, -9	Other chemical product and preparation
333	Machinery

As the share of VC funding captured by patent-intensive manufacturing industries declined, some of that share shifted into the non-patent-intensive industries, which include such categories as food, beverages, and textiles. Table A shows these comparative trends.

Table A: Share of VC Funds Invested Each Year in Manufacturing Industries by Patent Intensity

	USPTO Patent Intensive Manufacturing Industries	USPTO Non-Patent Intensive Manufacturing Industries
2004	50.45%	1.41%
2005	45.87%	2.33%
2006	45.10%	2.72%
2007	45.18%	2.53%
2008	42.62%	2.29%
2009	45.35%	2.98%
2010	40.59%	3.25%
2011	32.71%	3.39%
2012	32.39%	4.18%
2013	31.47%	3.43%
2014	26.36%	2.86%
2015	25.08%	4.52%

When considering this data, one can see that although the non-patent-intensive manufacturing industries gained in the share of funding, they still only account for a small portion of VC funding. Where else did funding shift besides to less patent-intensive manufacturing industries? The next section provides a more comprehensive analysis across broad industry sectors.

Broad Industry Sector Trends in VC Investment

The fact that money and deals are going relatively less often to patent-intensive manufacturing industries leads to the question where they are flowing. The answer, in short, appears to be largely to software.

The analysis in this section considers all venture capital deals in the Pitchbook sample across all industries. We identified four high-level industry sectors represented in the Pitchbook data:

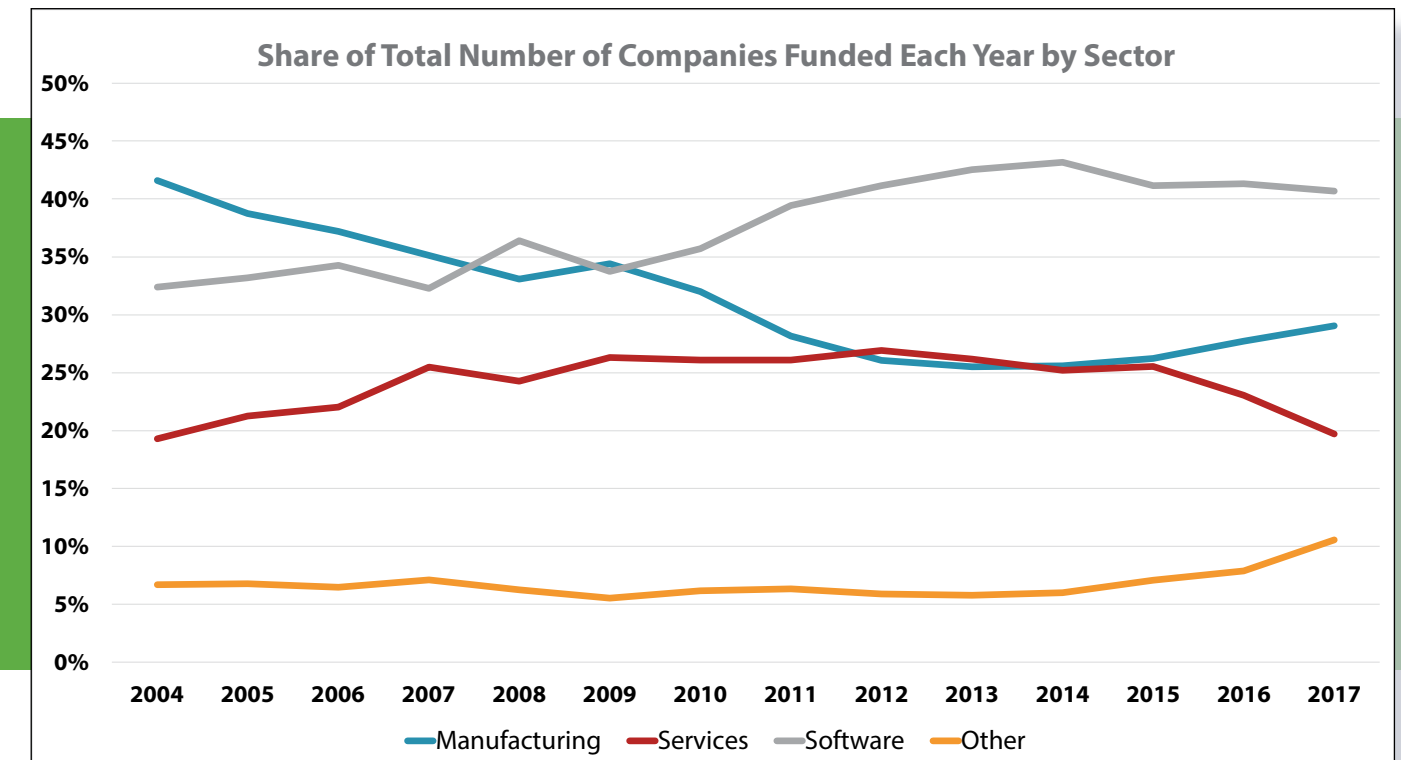
- Manufacturing (comprising the patent-intensive and non-patent-intensive industries analyzed in previous section)
- Software
- Services
- Other¹⁶

Table B: Share of Total Number of Companies Funded Each Year by Sector

	Manufacturing	Services	Software	Other
2017	29.05%	19.70%	40.69%	10.56%
2016	27.74%	23.05%	41.33%	7.88%
2015	26.23%	25.55%	41.16%	7.07%
2014	25.61%	25.21%	43.17%	6.01%
2013	25.51%	26.17%	42.52%	5.80%
2012	26.06%	26.92%	41.14%	5.89%
2011	28.17%	26.08%	39.43%	6.33%
2010	32.02%	26.09%	35.72%	6.18%
2009	34.41%	26.32%	33.74%	5.53%
2008	33.08%	24.26%	36.41%	6.26%
2007	35.12%	25.50%	32.28%	7.10%
2006	37.21%	22.03%	34.27%	6.49%
2005	38.76%	21.26%	33.19%	6.79%

¹⁶ "Other" includes six categories, all of which had relatively and consistently low levels of VC activity, and so were aggregated into a single category: Repair & Installation of Equipment; Mining, Natural Resource Extraction, and Processing; Distribution & Sales; Telecommunications Activities; and Miscellaneous, which includes a few hard-to-categorize categories such as building construction and categories designated as "other" by NVCA-Pitchbook without sufficient description to place elsewhere.

Figure 5: Share of Total Number of Companies Funded Each Year by Sector



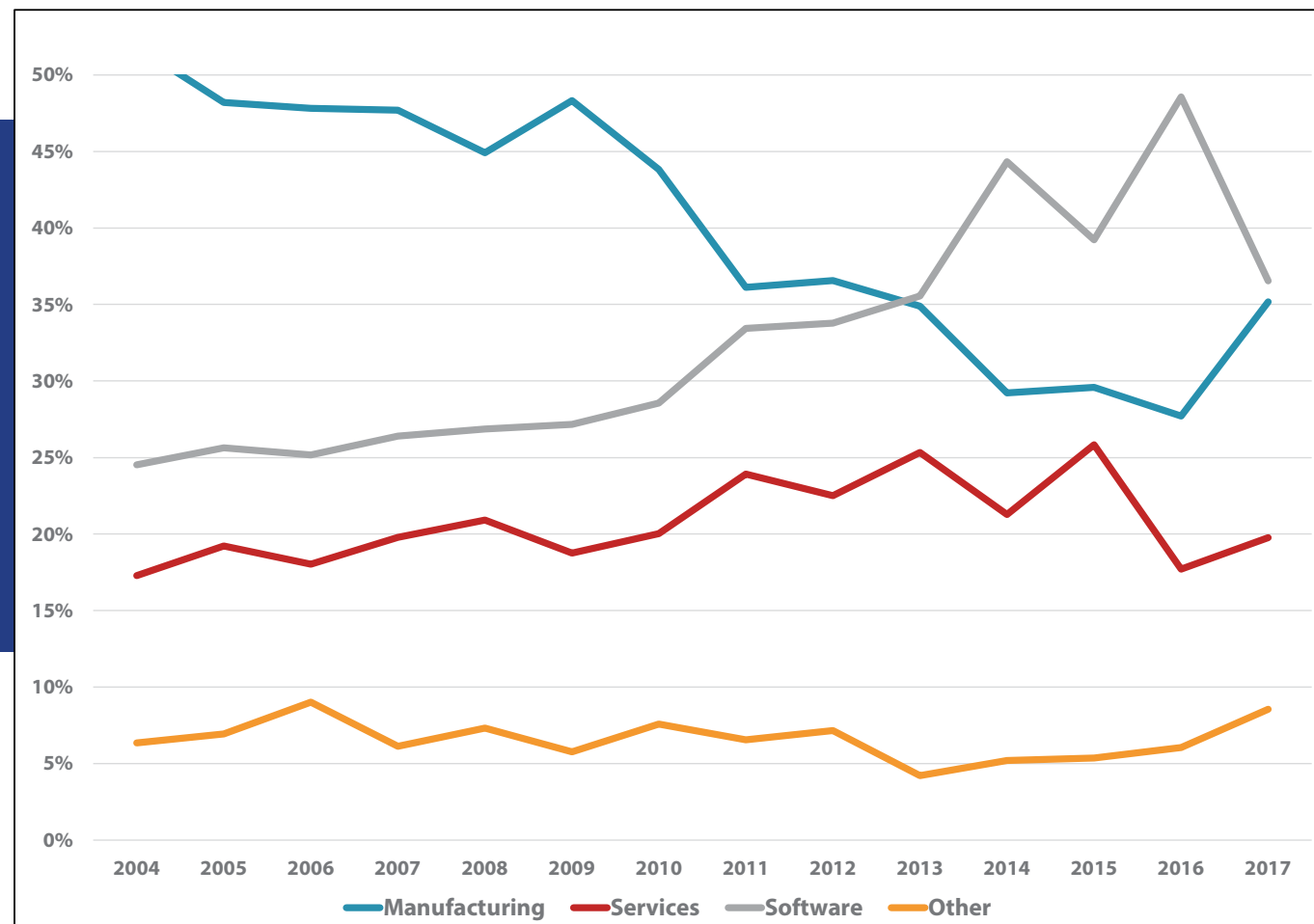
In terms of interest captured by venture capital, software companies have supplanted companies in the more patent-intensive manufacturing sector. In 2004, manufacturing companies represented about 42% of all companies funded by VC, while software companies represented about 32%. By 2017, the two industries had essentially switched places, with manufacturing at a 29% share and software at about 41%.

Money (or at least the relative share of it) also flowed away from manufacturing companies, largely to software companies. In 2004, manufacturing companies received about 52% of all venture dollars. That share dropped to 35% in 2017. Meanwhile, software climbed from a 24.5% share in 2004 to a 36.5% share in 2017.

However, not all software companies have benefitted equally. As the next section explains, Pitchbook's data shows that Social Network/Platform companies have captured the lion's share of growth of funding in the software sector, while some other software categories have lost share.

Moreover, as noted in the previous section, companies in the less patent-intensive manufacturing industries are receiving a larger share of venture capital funding than in the past.

Figure 6: Share of Money Invested Each Year by Sector



One question prompted by this analysis is whether it tells us anything about investment in patent-intensive industries. After all, unlike the data in the previous section regarding patent-intensive manufacturing industries, these four categories are not defined in terms of patent intensity. Nevertheless, this breakdown by industry sector also indicates that investment is moving toward less patent-intensive industries.

Research indicates that manufacturing industries are indeed the most patent-intensive, much more so than software or services. Determining patent-intensity is no simple matter, as the handful of studies that have examined patent-intensity, including the USPTO's study, were complex and extensive. The ones that exist, however, indicate stark differences among manufacturing, software, and services sectors regarding patent intensity.

Graham (2018) used U.S. patent and US Census data to construct a longitudinal database tracking inventors and patent owning firms over time from 2000 – 2011, matching patent grants to firms. Among other things, that study confirmed the conventional wisdom that manufacturing firms are more likely to obtain patents via grant or assignment.

The EUIPO conducted an extensive study that measured patent-intensity across all industries in Europe. The results largely confirm that manufacturing industries are the most patent-intensive, with a few exceptions. Like the USPTO, the EUIPO classified all industries above the mean for its patent intensity indicator as patent-intensive industries. Unlike the USPTO, the EUIPO averaged far more industries, so its set of patent-intensive industries is larger.

The additions the EUIPO found largely tracked the USPTO results, with a few additions. The EUIPO found that most of the patent-intensive industries, over 81% of them (in terms of categories), are in the manufacturing sector. It also included IP licensing and R&D firms in this category, as well as mining and natural resources. Software publishing (other than games) makes it onto the EUIPO's list, but it is, on average, the least patent-intensive of the EUIPO's patent intensive industries (i.e., just barely above the mean for all industries).

What these studies of patent intensity allow us to conclude is that of the four categories examined in this study — Manufacturing; Software; Services; and Other, only Manufacturing can be considered clearly and consistently patent-intensive.¹⁷ Most important for the purpose of this Report, the difference between manufacturing and software in patent intensity reflects conventional wisdom and legal advice. It is typically stated that software is usually best protected with copyright, trade secrets, the reputation embodied in a trademark, or a business model (such as subscription), rather than patents.

In sum, the move of investment away from manufacturing to software represents a move away from a patent intensive sector and toward one where patents are considered less relevant and essential.

Analysis of Selected Industries Winning and Losing Share of VC Funding

Another useful way to analyze venture capital investment trends is to look more closely at specific industries and industry segments. While trends in broad sectors are informative, the industries in which investment has declined relatively are important to note for the public policy discussion. In particular, investment in the life sciences sector, semiconductors, and computer hardware has declined in relative terms, and in some cases, even in terms of nominal dollars invested.

¹⁷ Further information is supplied in Appendix 1, which discusses methodology.

Industries Winning and Losing Share of Funding

To create representative and useful comparisons, we focus here on several industries that either significantly gained or lost in terms of the share of venture capital funding invested. Since the Pitchbook dataset breaks industries down into over 200 categories over 14 years, presenting a smaller set of representative industries helps clarify trends.

We built this comparison as follows:

First, we chose the industries in our sample that had started out with at least a 1% or more share of venture capital funding. In aggregate they received over 60% of total funding for the periods examined.

Second to avoid a single year or large deal skewing results, we took a conservative approach and compared the share over the first 5 years (2004- 2008) with the share over the final 5 years (2013 - 2017) of the sample.



Table C: Industries Winning & Losing Share of Venture Capital Funding since 2004

Industry Sector	Share of All VC Funding 2004 -2008	Share of All VC Funding 2013 - 2017	Percentage Change
Industry Sectors Gaining Share			
Financial Services	1.6%	4.1%	147.1%
Food and Beverage	.4%	1.5%	248.5%
Healthcare Technology Systems	1.2%	2.6%	112.6%
Restaurants, Hotels and Leisure	.4%	1.4%	266.5%
Software	25%	40%	57.6%
Total	28.6%	49.6%	
Industry Sectors Losing Share			
Computer Hardware	3.4%	1.2%	-63%
Healthcare Devices and Supplies	10.7%	6.2%	-42.6%
Pharmaceuticals and Biotechnology	15.6%	12.4%	-20.1%
Semiconductors	3.4%	.6%	-82.7%
Total	33.1%	20.4%	

Several things are notable about these results:

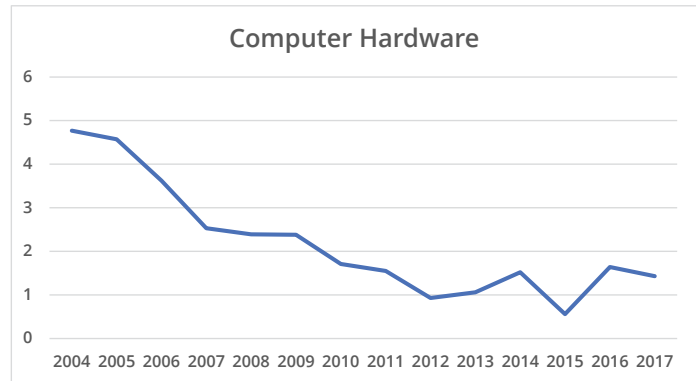
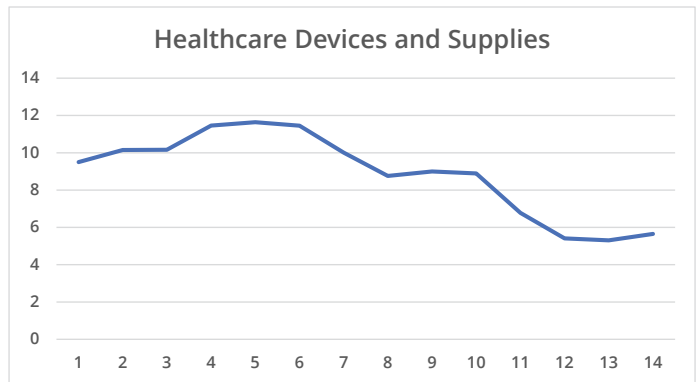
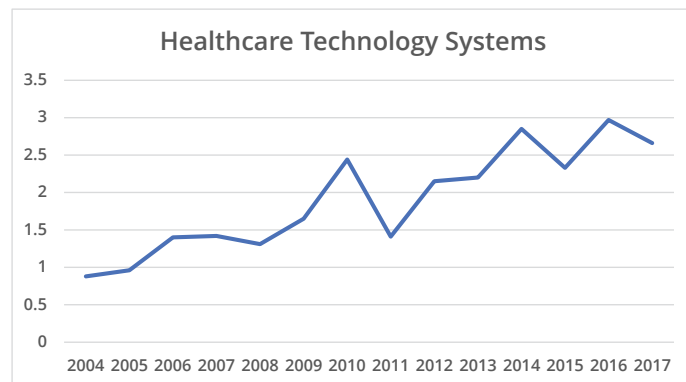
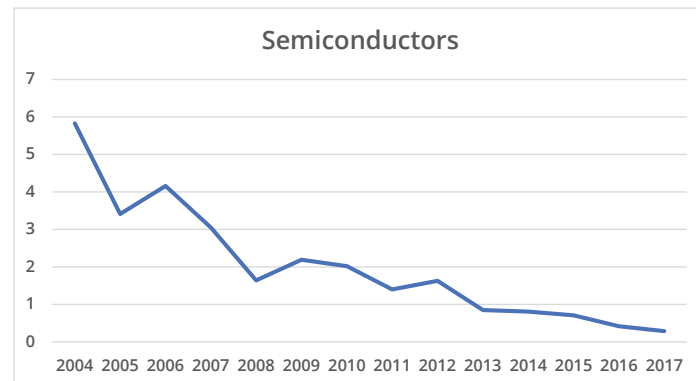
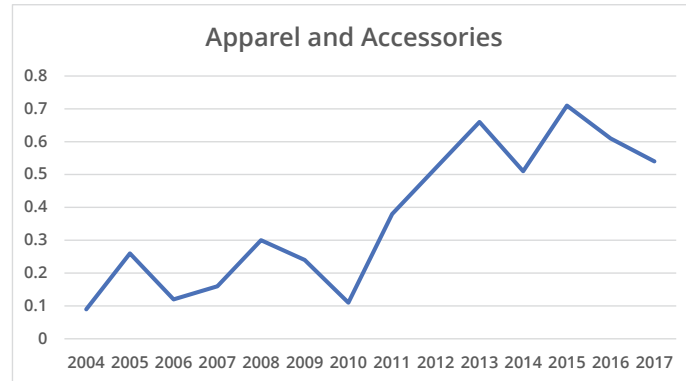
- Generally, less patent-intensive sectors such as financial services, food and beverage, and restaurants, hotels and leisure are attracting a significantly larger share of investment in recent years.
- Funding for businesses developing high tech hardware, such as computer hardware and semiconductors has dropped significantly. In fact, companies creating semiconductors receive less funding in both relative and absolute terms, as they received about \$1 billion less in funding during the later period than the early period. The share of investment in fashion and apparel and companies (not shown here) has grown by over 200%, and now matches that of semiconductor companies at .6%.
- Within the financial services sector, the big gains went to consumer finance, which increased from a .2% share in the early period to a 1.6% share of all funding in the later period – a nearly 700% increase.
- Software investment, while already strong in the earlier period, has increased significantly. Within the software sector there were gainers and losers as well. Most notably, the share of investment going to social network/platform software has increased greatly, going from 1.7% to a 7.9% share of all venture capital investment.

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 has experienced a 20% decline. In fact, the numbers are buoyed by a rebound in the biotech sector during the last few years. However, that relative share is lower than at the start of the study period.

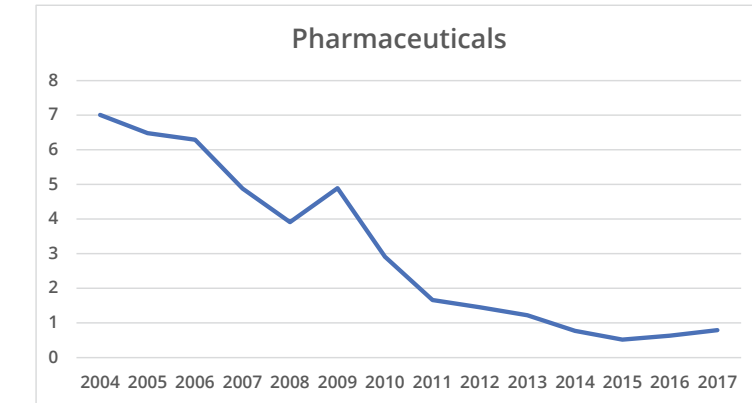
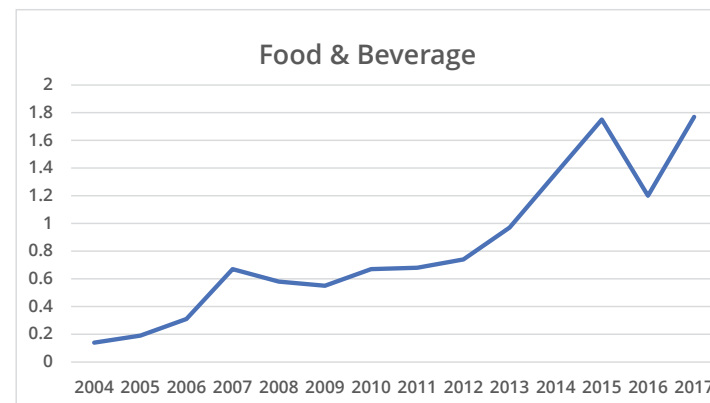
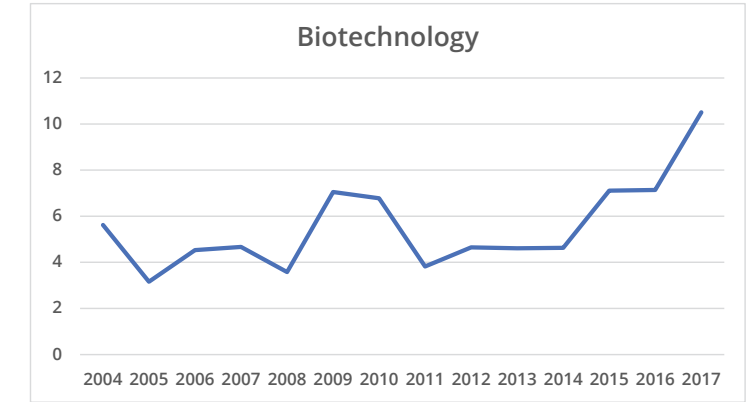
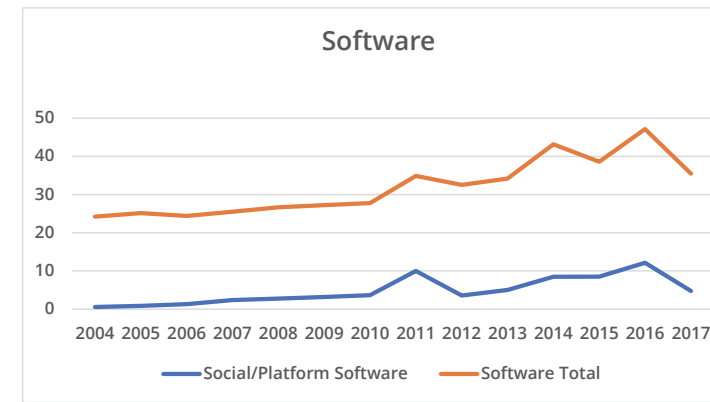
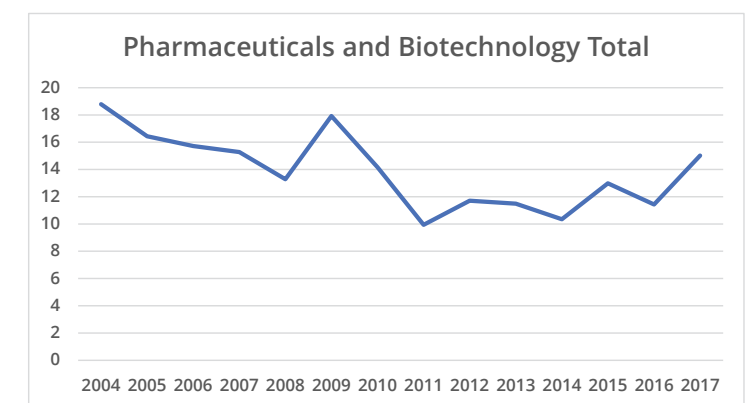
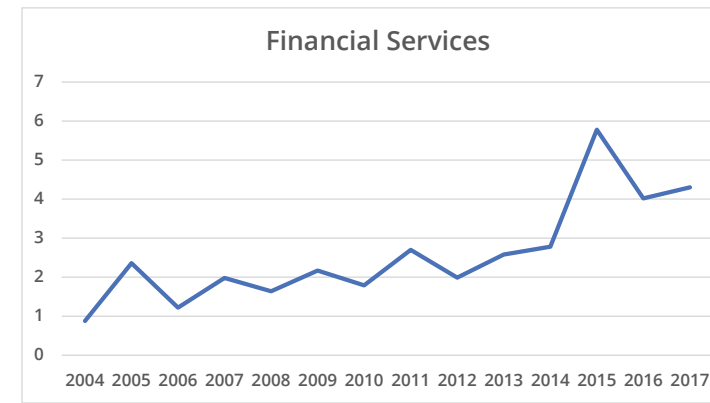
The share of investment in healthcare information technology, which can be protected by means other than patents, has grown, while other healthcare-related investments have seen a decline. We break down life sciences investment further in the next section.

Year-to-Year Trends, 2004 – 2017 by Industry

The following figures depict year-to-year trends, which further illustrate the points above. With the exception of biotechnology, which shows an increase in the share of funding the past few years, patent-intensive industries have received a smaller share of VC funding, while the non-patent-intensive have received a greater share.

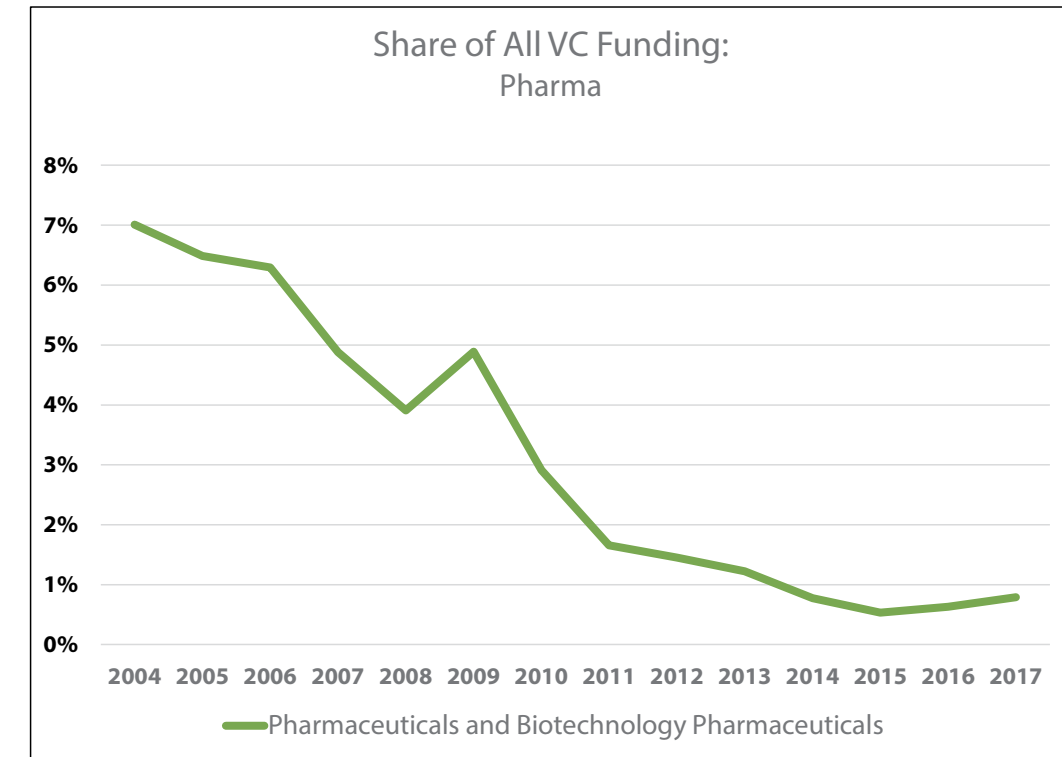


Year-to-Year Trends, 2004 – 2017 by Industry, continued



The data show a precipitous decline in the relative share of funding going to companies working on medical devices, drug discovery, and pharmaceuticals. The biotech sector has rebounded in the last few years, buoying the total for the entire sector. However, the combined relative share for biotech and pharmaceuticals – investment in the development of new treatments – is lower than at the start of the study period.

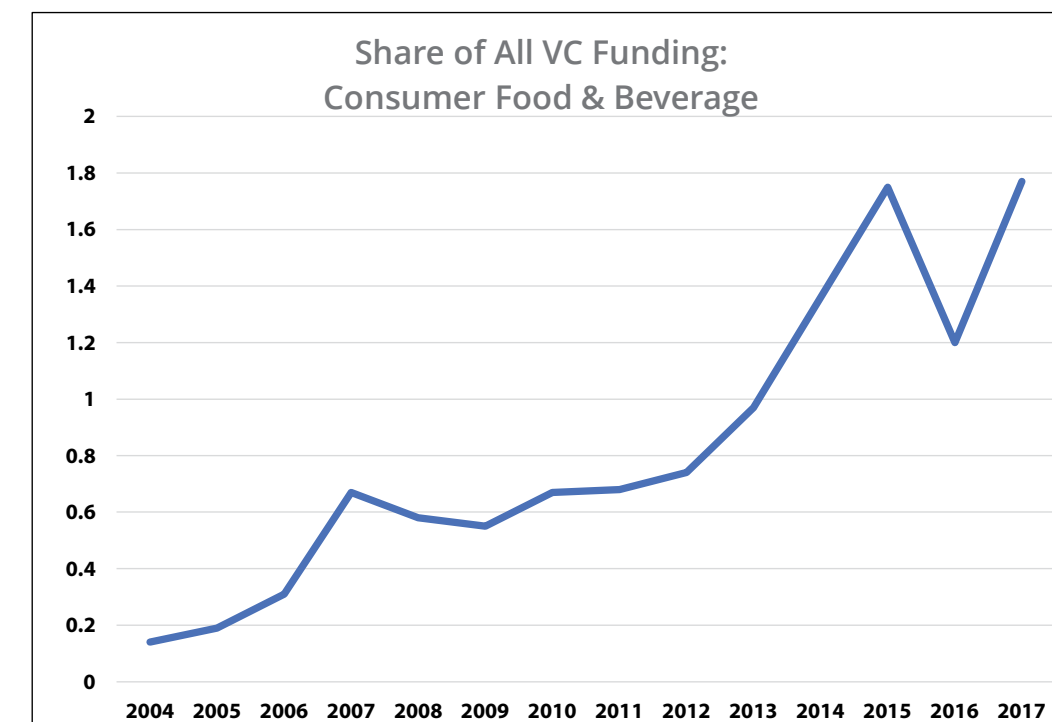
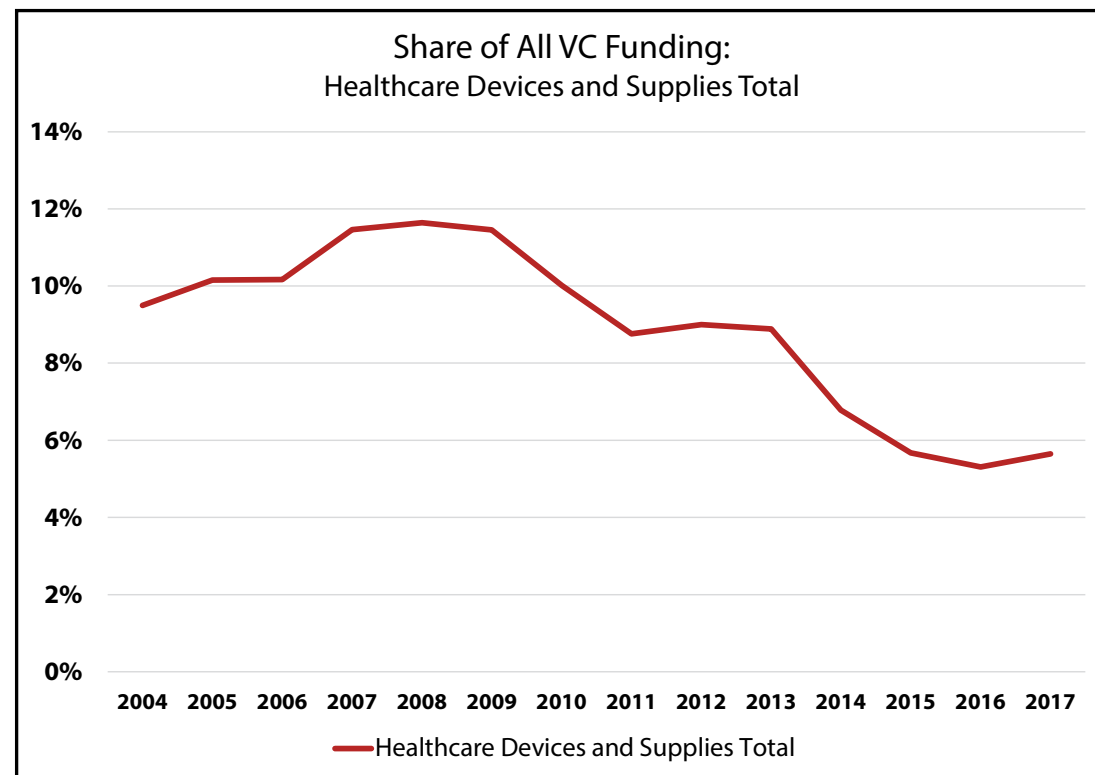
Healthcare Devices & Supplies	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Diagnostic Equipment	1.57%	2.29%	1.60%	2.20%	2.16%	1.53%	2.37%	1.51%	1.63%	1.64%	1.36%	1.21%	1.14%	1.47%
Medical Supplies	1.30%	0.63%	0.88%	0.84%	0.51%	0.39%	0.37%	0.40%	0.76%	0.29%	0.22%	0.29%	0.21%	0.18%
Monitoring Equipment	0.54%	0.55%	0.75%	0.59%	0.75%	0.69%	0.46%	0.46%	0.68%	0.90%	1.71%	0.72%	0.50%	0.58%
Other Devices & Supplies	0.57%	0.64%	0.51%	0.73%	0.54%	0.54%	0.29%	0.50%	0.64%	0.56%	0.25%	0.91%	0.31%	0.31%
Surgical Devices	2.67%	3.21%	3.56%	3.42%	3.39%	3.63%	3.17%	3.01%	2.44%	2.62%	1.68%	1.10%	1.38%	1.39%
Therapeutic Devices	2.85%	2.85%	2.86%	3.69%	4.29%	4.67%	3.36%	2.88%	2.85%	2.89%	1.56%	1.45%	1.77%	1.72%
TOTAL	9.50%	10.15%	10.16%	11.46%	11.64%	11.45%	10.01%	8.76%	9.00%	8.89%	6.78%	5.67%	5.31%	5.65%
Pharmaceuticals & Biotech	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Biotechnology	5.62%	3.16%	4.53%	4.67%	3.58%	7.05%	6.78%	3.82%	4.65%	4.61%	4.63%	3.33%	7.14%	10.51%
Discovery Tools (Healthcare)	0.96%	0.74%	0.11%	0.34%	0.65%	0.47%	0.27%	0.46%	0.06%	0.24%	0.22%	0.15%	0.14%	0.03%
Drug Delivery	0.69%	0.92%	0.90%	1.32%	1.53%	0.89%	0.52%	1.05%	0.93%	0.93%	0.43%	0.27%	0.51%	0.42%
Drug Discovery	4.27%	4.63%	3.69%	3.81%	3.23%	4.38%	3.29%	2.78%	4.45%	4.45%	4.20%	1.61%	2.99%	3.27%
Other Pharmaceuticals & Biotechnology	0.24%	0.51%	0.20%	0.26%	0.38%	0.24%	0.39%	0.17%	0.18%	0.03%	0.09%	0.21%	0.03%	0.01%
Pharmaceuticals	7.01%	6.48%	6.29%	4.88%	3.91%	4.89%	2.91%	1.66%	1.45%	1.22%	0.77%	0.53%	0.63%	0.79%
TOTAL	18.79%	16.44%	15.72%	15.28%	13.28%	17.92%	14.16%	9.94%	11.71%	11.49%	10.35%	6.11%	11.43%	15.02%



The share of investment going to pharmaceuticals and drug discovery has also declined, although it appears that some of that investment has shifted to biotech. Pharmaceuticals went from a 7% share in investment in 2004 to a .79% share in 2017. However, the total share of investment of going to pharmaceuticals and biotech together has declined.

In sum, with the exception of a rebound in biotechnology investing in 2016 - 2017, investment in the life sciences has fallen.

In contrast to the share of investment going to the life sciences industry, various consumer products industries have fared well. For example, consumer apparel, and consumer food and beverage have both seen marked rises. In fact, the consumer food and beverage category now receives a greater share of VC investment than pharmaceuticals.



Part IV: Case Studies: Innovators and investors in Patent-Intensive Industries

Our case studies of innovators and investors provide a first-hand account of the importance of an effective and reliable patent system to ensuring that the world continues to enjoy access to new technologies that save and enhance lives. We were able to talk to a diverse group of successful individuals.

They were united in their message that the patent system is essential to ensuring that the public has access to the kind of technologies that are essential to resolving the current crisis and saving lives in the future.

In the case studies that follow, we further explore these issues discussed in this report, letting the subjects explain for themselves.

Case Study: Eb Bright, ExploraMed

Over the last two decades, Eb Bright has been an innovator in the medical device field, working with his colleagues to successfully launch six companies and their products. He has seen the medical device business from many perspectives as a lawyer, investor, innovator, and business leader. During that time, Bright and his colleagues have enjoyed continued success in developing products that benefit patients, but the nature of those products has changed as the nature and reliability of intellectual property protection has changed.

Bright started his work in the medical device field as a patent attorney in private practice, eventually leaving his firm to join the medical device company Guidant as its first patent counsel. At Guidant he had the opportunity to get closer to both the technology and business of medical devices. His role grew with the business, as he became involved in business development and worked on spinouts and investments. Eventually, Guidant was purchased by Boston Scientific and Abbot in a \$27.2 billion blockbuster deal. Bright decided he preferred working with startups to continuing to work with the bigger company, so he left Guidant in [2005] to join ExploraMed, a medical device company incubator founded by Josh Makower.

ExploraMed's business model is to launch and establish companies that produce new medical devices. ExploraMed starts by raising a fund to support the launch of new companies. It raised its first fund in 1996 and recently finished raising its fifth. ExploraMed focuses on identifying unmet health needs, creating a novel solution, and incubating a startup company that develops the solution. ExploraMed has launched eight companies since it raised its first fund, taking most of them to successful exit events, where the company was purchased. It is currently working on new solutions since closing funding on its fifth fund.

The mission of ExploraMed is to “to significantly improve the quality of life for patients through unique solutions to long-standing health issues or concerns.”¹⁸ It executes this mission through an innovation process that starts with identifying and defining an unmet health need that it can significantly improve with a new invention. The ExploraMed team's work is thus driven by applied research, starting with a problem they seek to find the best way to solve.

Over the past 15 years, ExploraMed has launched a number of successful companies, including:

Acclarent, which pioneered the field of Balloon Sinuplasty to treat chronic sinusitis. This condition is one of the most common health problems in the U.S., affecting over 35 million people each year. Johnson and Johnson acquired Acclarent in 2010.

Neotract, which addressed one of the most common ailments of men over 50 — urinary tract symptoms — due to enlarged prostate (benign prostatic hypertrophy) with an implant known as UroLift. The FDA cleared UroLift in 2013, and Teleflex purchased the company in 2017.

Moximed, which treats early osteoarthritis for the knee through an implant that is an alternative to drugs and eventual knee replacements. The Atlas System implant is currently available in Europe and now in clinical studies in the U.S.

Willow, which produced the first all-in-one cordless breast pump. The Willow breast pump allows women a much higher level of discretion and convenience.

Intellectual property protection directs and shapes the potential solutions developed by Bright and his colleagues. For medical devices, patents are very important because the invention is revealed by the device and by publications that they make to encourage use of the device and advance knowledge in the field. If they cannot protect their invention with IP rights, they cannot proceed.

Bright sees an effective intellectual property strategy as part of his and ExploraMed's responsibility to investors:

“We are using the money of limited partners, who are often retirement funds. They purposely allocate part of their funds to higher risk investments such as venture capital seeking a higher return, but the retirement plan's investors trust it to pick a venture capitalist who will make good choices. Part of making good choices is ensuring that investments can be protected by effective intellectual property rights.”

Patent protection was essential to establish the confidence and patience it took to develop ExploraMed's earlier products. For many years, ExploraMed focused on implants, which take significant time and capital to bring to market because of lengthy development periods and significant clinical trials. For example, Neotract's UroLift took eight years from idea to FDA clearance in 2013, and four more years to a return on investment to its shareholders through the company being acquired. Meanwhile, Moximed started in 2007 and its Atlas System implant is still undergoing clinical trials in the U.S.

¹⁸ <https://www.exploramed.com/about-us>

Reliable patents were also essential to the confidence of later-stage investors and the stock market. For example, Neotract's UroLift was considered to have good patents, which was important to Neotract's successful exit event, a purchase by Teleflex. At the time of the purchase, Teleflex's CEO touted Neotract's strong patents to the public markets.

Bright is acutely aware of changes to the patent system in recent years. He cites the introduction of inter partes review, with its high reversal rates, as a factor that has put existing patents at risk. Other risk factors include difficulties with enforcing patents, particularly securing injunctions. Meanwhile, restrictions as to what subject matter can be patented have accumulated due to recent Supreme Court decisions that have made certain areas of research less feasible.

As a result of these changes, there has been a decrease in capital invested and less capital available to put at risk. While Bright and his colleagues are still innovating and succeeding, the type of products and solutions have changed.

Instead of implants, Bright and his colleagues have recently focused efforts on external devices that put investment at less risk. For example, the Willow breast pump required far less development time and capital because it was not subjected to the lengthy and expensive clinical trials required for implants. Also, ExploraMed relied on trade secrets embodied in Willow's firmware, rather than patents, to protect its investment. The ExploraMed team has not completely closed the door to high-risk products such as implants, but they say the prospects are more challenging compared to the past. For example, the emerging field of bioelectronic medicine is intriguing from a scientific standpoint but patent eligibility concerns make it less interesting from an investment standpoint.

"It's a shame," Bright says, "as I would love to work on bioelectronic medicine. We could do things to address inflammatory conditions without drugs. However, it's still early days, and the science is uncertain. In the best of circumstances, that makes it hard to attract capital. Add the uncertainty about patentability, and we have decided not to pursue these inventions at this time."

Bright is hearing similar things from venture capital investors. They are passing on investments in early stage life sciences companies that they might have done before, since risk regarding patents has changed the calculation. "Many factors go into deciding whether to make an investment," Bright said, "but adding patent vulnerability to the mix often tips the balance toward passing on a deal."

In the end, however, ExploraMed is still launching products and investors are still making investments. Why then, should the public and policymakers be concerned about the changes Bright describes?

Bright says they should care because "of the disease conditions that are not being researched." Changes to the patent system have pushed ExploraMed and others to focus more attention on products such as Willow that affect quality of life rather than products that save lives. "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."

"These high-impact types of diseases are not being addressed like they would have been previously," says Bright. "Everybody is less well off."

Case Study: Josh Makower, ExploraMed & New Enterprise Associates

Josh Makower has been successfully developing medical device companies since he graduated from NYU medical school in 1989, working as an inventor, entrepreneur and venture capitalist. He is about to spin out his tenth company from the incubator he founded, ExploraMed, that he now runs with Eb Bright (who is also profiled in this paper on page 38).

In 1999, Makower helped launch the Stanford Biodesign program, which teaches medical engineering using his methodology for solving unmet medical needs with patentable innovation. The program uses a textbook he created, which has been adopted by leading medical bioengineering programs around the country.

In the course of his work, Makower has been a prolific inventor. He holds over 300 patents and patent applications for various medical devices in the fields of cardiology, ENT, general surgery, drug delivery, obesity, orthopedics, women's health, and urology.

One of his first successful ventures was an implant for treating incontinence and gastroesophageal reflux, problems suffered by tens of millions of patients. This small and very successful implant, was an example of ExploraMed's approach to meeting unmet needs of large numbers of patients, as previous devices required invasive surgery or used material that was too easily absorbed into the body.

Another early success was TransVascular, Inc., a startup that developed a platform for delivering treatments to the cardiovascular system, including a catheter and ultrasound imaging system. When Medtronic acquired the technology in 2003, it described the novel device's important potential for facilitating other key therapies, such as delivering "therapeutic agents, including cells, genes and drugs to precise locations within the vascular architecture." One particularly promising application was repairing the damage from heart attacks suffered by 1.5 million patients a year by delivering stem cells and other agents.

Makower's other successes are profiled in this report's discussion of his work with Eb Bright, who joined ExploraMed in 2005. Makower and Bright have consistently sought out unmet medical needs and successfully developed many innovative, high-impact solutions that improve the lives of millions of patients.

Makower's success as an entrepreneur led him into the venture capital world. While still playing a role at ExploraMed, he is now also a general partner at New Enterprise Associates (NEA), one of the world's leading venture capital firms. He has worked with NEA since he began as an entrepreneur-in-residence in 1995. Since then, NEA has been a financial partner for ExploraMed's many successful businesses. In 2015, NEA invited him to become a general partner, and he now runs NEA's medical device practice.

“WHAT IS REALLY TROUBLING IS THAT AN IPR CAN SHOW UP AFTER 5, 10, OR 12 YEARS OF DEVELOPMENT, AFTER LOTS AND LOTS OF INVESTMENT, RIGHT AT THE TIME OF COMMERCIALIZATION. THIS HAPPENS AFTER THE BUSINESS HAS TRAVERSED THE CHALLENGES OF FDA APPROVAL AND REIMBURSEMENT BARRIERS. IT'S JUST DEVASTATING, AND IT DESTROYS ALL THIS INVESTMENT. IT MAKES THE UNPREDICTABILITY OF THE PATENT SYSTEM A THREAT TO EVERY ASPECT OF THE LIFE SCIENCES ECOSYSTEM”

- Josh Makeover, Executive Chairman of ExploraMed and General Partner of New Enterprise Associates

One consistent feature of his work has been the need for reliable intellectual property protection, both as an entrepreneur and a venture capital investor. **“IP protection is absolutely essential,” says Makower. “We will not do a project without it. These projects take so long, that you can’t do it without this protection.”**

The availability of IP protection shapes the choices he makes as an entrepreneur and investor — in other words, which unmet medical needs get addressed. “If we can’t invent something novel, we do not do it. It shapes our investment choices and how we innovate. It’s a relatively binary check. The IP needs to be there, and the product needs to be non-infringing.”

In recent years, changes to the patent system have made it more difficult to launch innovative products. Makower explained that the inter-partes review system, meant to provide a less expensive way to challenge patents, has been used by competitors to financially drain smaller companies with successive and serial challenges to their patents. “Big incumbents have used IPRs to stall competition. Even when they lose, they keep coming with additional attacks.”

Serial IPRs have hurt Makower’s own startups. “In the ExploraMed portfolio, two companies have faced a larger competitor that used the IPR system to liquidate the cash reserves of those companies. In each instance, these proceedings stalled a liquidity event. It has been frustrating. In at least one case, it likely will end the business.”

The prospect of weaponized IPRs has also affected his ability to invest in disruptive companies as a venture capitalist. “In one instance, we considered investing in a small competitor, but saw that a big competitor would be likely to challenge its patents. We believed that the small company had a strong case, but the potential need to spend money on litigation rather than innovation gave us pause. In the end, we did not invest due to the threat.”

He sees investors as more risk averse due to IPRs and changes in patent eligibility. With that comes a substantially negative impact on job creation and the improvement of medicine.

Patents are harder to obtain than in the past. “If there is a way to get it, we get it, but we do worry about whether claims are allowable.” In his view, “rigor in patenting is not bad, but things have become a little too hard.”

The difficulty in getting patents changes choices as to how to innovate and invest. For example, he worries that one of his early successes, TransVascular, might not be possible today. He perceives small, but important changes, as being harder to patent. TransVascular represented a set of exactly such changes — small changes that made it much easier to deliver treatments to repair the vascular system.

Today, he thinks launching a small company like TransVascular would be much more challenging, and any possible exit would be much less likely to happen. “Stepping into a space with large incumbents could mire a small company in patent litigation.”

“It’s a much more vicious world for small entities with smaller bankrolls. It squashes innovation.”

According to Makower, pervasive patent risk is holding back investment and innovation in the life sciences. “It makes every deal riskier, which has to be factored into every decision, from development, to investment, to evaluation, to exit.”

Deterring innovation hurts everybody, Makower says: “First and foremost, neither the healthcare system nor available treatments are ideal. We all experience pain and suffering that does not need to exist. If innovators can reduce health care costs, more people get treated. If innovators can develop better treatments, more people get healthier. Fundamentally, all these changes to the patent system affect our health and quality of life.”

Makower also decries the economic impacts of making patents less reliable. “Weakening the patent system takes away jobs. It hurts America’s position within the global economy. These policies have been promoted by the largest companies in the world. For them, serial IPRs are cheap, so they can hold onto market share by draining small companies. If this continues, America will become a country of large, monolithic, slow, and not very innovative companies. That’s not what the American dream is about.”

“FIRST AND FOREMOST, NEITHER THE HEALTHCARE SYSTEM NOR AVAILABLE TREATMENTS ARE IDEAL. WE ALL EXPERIENCE PAIN AND SUFFERING THAT DOES NOT NEED TO EXIST. IF INNOVATORS CAN REDUCE HEALTH CARE COSTS, MORE PEOPLE GET TREATED. IF INNOVATORS CAN DEVELOP BETTER TREATMENTS, MORE PEOPLE GET HEALTHIER. FUNDAMENTALLY, ALL THESE CHANGES TO THE PATENT SYSTEM AFFECT OUR HEALTH AND QUALITY OF LIFE.”

- Josh Makeover

Case Study: Dr. Derrick Rossi,¹⁹ Moderna, Magenta, Intellia, and Convelo Therapeutics

Dr. Derrick Rossi is a leading innovator doing work on some of today's most promising and exciting therapies in the life sciences. Dr. Rossi, currently the CEO of the biotech startup Convelo, also helped found three other promising startups that are working to bring cutting-edge treatments to patients: Moderna, Magenta Therapeutics, and Intellia Therapeutics.

These treatments promise to use stem-cell science, gene editing, and other cutting-edge sciences to bring long-hoped for treatments and cures to patients. These technologies are fundamental enough to be applicable to a wide range of conditions, including cancer, multiple sclerosis, Zika, heart failure, and diseases affecting the liver, eyes, muscles, and central nervous system.

While his primary focus has been transformative science that promises to help patients, he cites intellectual property as the foundation that enables him and his colleagues to bring research from lab to market to patients.

Dr. Rossi has seen innovation from several perspectives, starting with its birth in a university lab, to spinout to a startup, to successful public offering. He served as a faculty member at Harvard's Medical School and its Department of Stem Cell and Regenerative Biology, doing stem cell research. After helping to commercialize his own work as an academic founder of several startups, he eventually left academia to serve as CEO of Convelo.

He began his work as a researcher but was always directed toward the practical goal of delivering treatments. His passion is good science that leads to treatments for patients with unmet clinical needs. Reflecting on his success so far and the promise it holds for patients, he observed that "It's fun to think about how simply reading a cool paper on pluripotent stem cell science could lead to all of this."²⁰

Dr. Rossi and his research have been at the heart of several transformative companies, including:

Moderna, which arose from Dr. Rossi's work on what he characterized as a "side project" based on his interest in the work of Nobel Prize winner, Shinya Yamanaka, who first showed that mature cells could be reprogrammed back to their embryonic state. Dr. Rossi hoped to use this discovery to create treatments that used the human body's own ability to produce therapeutic proteins, but there were many obstacles to overcome. Dr. Rossi and his team engaged in laborious research and ultimately discovered a way to modify messenger RNA (mRNA) so that the body no longer recognizes it as a viral attack. This allowed them to use mRNA to convey "instructions" to induce cells to make a desired protein, including, crucially, antibodies to fight viruses.

The potential of this innovation is vast. Since it can be used to express any protein, it could treat thousands of diseases.

What excites Rossi is that Moderna has over 20 treatments in clinical development. It has achieved multiple successful phase 1 trials and has ongoing phase 2 trials for treatments such as cancer vaccines and treatments for rare diseases. He says, "when we finally make an improved medicine, then I will be satisfied."

Since we talked to Dr. Rossi, Moderna has become the topic of worldwide attention and frequent news, as it was the first company to bring a potential Covid-19 vaccine to human trials. As of this writing, its Covid-19 vaccine is about to enter phase 3 trials.

Once Dr. Rossi had the experience of "doing work that could be spun into a biotech and brought to patients," he found it "addictive."

And so, he has continued to innovate.

Magenta was launched in 2016 with venture funding to try to cure blood cancers and other disorders, autoimmune diseases and other genetic diseases that have shown a response to an immune system reset through bone marrow transplant. Unfortunately, these transplants are unavailable for many patients and conditions, and the ones that receive them endure serious side effects.

Dr. Rossi saw a need for a change. He explained that "bone marrow transplants can be lifesaving, but they are also risky. One-year survival rates for patients with matched donors is 70% — unmatched is 55%."²¹

Magenta has developed a much more effective transplant regime, that combines a specially targeted antibody with a drug to prepare the patient for transplant. This development could allow the use of stem-cell transplants for a much wider range of disorders. The therapy even shows promise for transplants from unmatched donors.

Intellia is now a publicly held company working to move its therapies to clinical trials. It seeks to apply CRISPR/Cas9 technology to cure a number of diseases including various cancers and other diseases affecting the liver, eyes, muscles, and central nervous system.

Convelo is working to develop treatments to address the deterioration of the material that sheaths nerve fibers. This deterioration plays a role in multiple sclerosis and other nervous system disorders. Regeneration of myelin does not happen naturally, so a treatment that stimulated this regrowth would be transformative for many patients.

Convelo is partnering with larger life science companies to develop a plan for commercialization which is essential to bringing such a treatment to patients. "Moving drugs toward people is the goal. MS trials are big expensive trials, and anyone ultimately bringing an MS drug to market will need to spend hundreds of millions."

¹⁹ All quotations, unless otherwise cited are from an interview with Derrick Rossi conducted on December 4, 2019.

²⁰ The Science of Startups: Drs. Derrick Rossi and Paul Tesar Discuss How Their Biotechs Are Bringing Stem Cell Research to Patients, New York City Stem Cell Foundation, March 26, 2019, <https://nyscf.org/resources/the-science-of-startups-drs-derrick-rossi-and-paul-tesar-discuss-how-their-biotechs-are-bringing-stem-cell-research-to-patients/>

²¹ Ibid.



The Role of Intellectual Property

Dr. Rossi focuses first and foremost on strong science and unmet clinical needs, but he observes that intellectual property is a support and foundation for the work of bringing new treatments to patients. He said, “you can be working on the coolest thing, but investors need to know that there is some protection for their investment, plain and simple.”

For a biotechnology startup and its investors, compelling science is the threshold condition, but the intellectual property is “the future prospect that reassures investors.” For Convelo, he wanted a robust portfolio of patent filings before engaging with pharmaceutical companies. It was not only to protect the company’s work prior to talking to potential investors, “but also to assure pharma that we had protectable assets. I put a massive push on this from day one.”

Dr. Rossi observed that while patents are essential to bringing a treatment from lab to patients, neither the final version of that treatment, nor the patents that protect it are likely to emerge from an academic setting. It is often the case that university research discovers the first step toward a treatment, but rarely, if ever, the particular treatment itself. Correspondingly, there is no patent on the yet-to-be developed treatment. Instead, there is both early-stage research and IP.

Convelo was a classic example of a startup built on early, foundational research that needed further development. The very early research that Convelo had licensed from Case Western showed a platform for drug discovery, but not a drug itself. Convelo would need to combine investment capital, a world-class team and significant additional IP to find and develop an effective treatment to launch. “As often is the case, you get that IP to get the initial investment, but you know full well that the real value will come post-launch of the company.”

In any event, said Dr. Rossi, “early patents have limited life because of how long it takes to market.” Clinical trials can consume many years of patent life before the drug ever gets to the commercial market.

WHEN ASKED WHETHER SOME ALTERNATIVE MECHANISM, SUCH AS GOVERNMENT FUNDING, COULD REPLACE PATENT-DRIVEN, COMMERCIAL DRUG DEVELOPMENT, DR. ROSSI REPLIES: “NOT A CHANCE. ACADEMICS ARE GOOD AT ACADEMIA AND FUNDAMENTAL SCIENCE. THEY ARE NOT GOOD AT DEVELOPING DRUGS FOR PATIENTS.”

According to Dr. Rossi, while many fundamental discoveries are made in academia, treatments that actually reach patients are developed by companies that need IP to protect them. “The really critical IP comes downstream.”

He lauds the role of commercial actors and investors in delivering treatments to patients. “This industry of professionals is out there... The more people who are involved in the chain, post-academic discovery, the more you have pros involved — all the way from IP filings to VCs to due diligence to assembling a team,” the more likely you are to develop a viable treatment.

When asked whether some alternative mechanism, such as government funding, could replace patent-driven, commercial drug development, Dr. Rossi replies: “Not a chance. Academics are good at academia and fundamental science. They are not good at developing drugs for patients.”

Moreover, the government would not manage the process well either. Dr. Rossi observes that even big pharmaceutical companies are often too bureaucratic to originate new treatments. “This is why biotech startups are the predominant way to develop new treatments. They are nimble, follow the data, make quick decisions, and focus on the problem without distraction.”

When asked what he thought of proposals to restrain the role of patents and commercial motivation in drug development, he replied that “taking away free market enterprise from the system would be a surefire way of messing it up. It would be a terrible idea.”

He observes that developing a drug “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.”

Case Study: Barney Cassidy, Juno Therapeutics

After a successful career in the innovation industries working in communications and semiconductors, Barney Cassidy joined his first life sciences company, Juno Therapeutics, where he was its 13th employee. As General Counsel, he focused on building a strong patent portfolio that set Juno up for a future acquisition, while defending Juno's rights during a challenging time for patent rights.

Juno produces a CAR T-cell therapy that uses the body's own immune system to fight cancer. It is a very effective therapy for some cancers, particularly Non-Hodgkins Lymphoma. Doctors extract T cells from the patient's blood to add an artificial receptor to the surface. This receptor enables the cells to kill cancer cells. Once they are returned to the patient's body, the cells multiply and attack tumor cells.

The therapy developed by Juno (which was acquired by Celgene, which, in turn, was acquired by Bristol Myers Squibb) recently concluded a successful clinical trial. In a study announced in December 2019, the therapy eliminated tumors in 53% of relapsed blood cancer patients and shrunk tumors in 73% of the patients.

One of the most important things about these results is that patients in this trial essentially were out of treatment options. They had relapsed after undergoing all other treatment options. Chemotherapy had not worked for two-thirds of them. Of the ones who achieved a complete response to Juno's CAR-T therapy, 86% of them were still alive one year after treatment and 65% of them did not see their cancer worsen.

As Cassidy says "we don't use the word 'cure' lightly, but this is a new approach to medical care using human cells. It changes everything for many patients."

Juno assembled a strong team, especially its six founders from three different institutions: Fred Hutchinson Cancer Research Center, the Memorial Sloan Kettering Cancer Center, or MSK, and the Seattle Children's Research Institute. Cassidy praised the founders for their ability to bring diverse perspectives to Juno that kept it "ruthlessly focused on data."

Cassidy also said that the other strength the founders brought to the table was intellectual property. They each brought patents or patent licenses to Juno, as well as know-how. When pooled the whole was greater than the sum of its parts." With the help of Cassidy and outside counsel, Juno continued to add to this patent portfolio, among other things, a key license from St. Jude.

Juno's patent portfolio was cited by many as one of the pillars of its success. Juno enjoyed consistently high valuations, driven in part by the strength of its patents. It was one of the best-funded startups in biotechnology history and it went public in 2014.

According to Cassidy, "the heart of the company was the IP that enabled us to develop the drugs we did." "It's unquestionable that it was absolutely imperative that we have strong patent protection. It took in the neighborhood of \$2.5 billion to develop this therapy, and we needed to secure that investment with patents."



DEMOCRATIC DECISION-MAKING IS DRIVEN BY PASSION, NOT BY SCIENCE, WHICH IS WHAT SHOULD DRIVE THESE DECISIONS.

THE PRIVATE INVESTOR HAS SOMETHING TO LOSE IF HE OR SHE GUESSES WRONGLY.



- Barney Cassidy, former General Counsel, Juno Therapeutics and Visiting Researcher at Harvard Law School

For Juno, patents did not just provide protection, but they also helped attract the investment needed to fund its tremendous development costs.

But the road was not always smooth and challenges did occur. One of them was a patent infringement lawsuit against a rival company, Kite. (Kite was eventually acquired by Gilead.) Bristol-Myers-Squibb, which by the time of trial had acquired the Juno patents, won the lawsuit in December 2019, securing a \$753 million verdict, which the trial judge recently increased to \$1.2 billion for willful infringement.

During the course of the dispute, Kite challenged Juno's patent in an inter-partes review proceeding. Although Juno won that proceeding, Cassidy was critical of the IPR system as it initially developed after it was established by the America Invents Act in 2011. "The purpose of the IPR system was to reduce litigation, but it became a playground for opponents." He observed that the system at first was very one-sided. For example, it only allowed the challenger to provide an expert's opinion at the institution of the proceeding. Another problem was the ability of challengers to file serial IPRs to tie up and undermine a patent — one after the other, rather than being required to bring all claims at once. Since then, the PTO has remedied some of these issues under its current Director, Andrei Iancu.

Nevertheless, according to Cassidy, problems with IPRs and other changes to the patent system have had negative effects on investment. Cassidy observes that they "have made it more difficult to obtain investment in early stage that have potential to bring disruption to the status quo... Many VCs decline to invest as broadly in early stage companies as they once did. Instead, they prefer to invest in later stage companies that have less exposure to patent challenges as an existential event."

As Cassidy observes, patent challenges for early stage companies drain precious investment dollars. A company facing a series of IPRs, for example, "faces a choice of funding litigation or innovation. There is a more direct tradeoff for early stage companies."

Cassidy heralds the patent system for the advances it brings, allowing the private sector to "decide how to develop the next generation of medical advances. Government has an important function in our society, but it is not equipped to make these decisions. **Democratic decision-making is driven by passion, not by science, which is what should drive these decisions. The private investor has something to lose if he or she guesses wrongly.**"

Case Study: Cleveland Clinic, Diagnostic Tools

Cleveland Clinic has found bringing its cutting-edge, life sciences research from the lab to patients more challenging in recent years, as changes to the patent system have made commercialization harder for investors and startups. In particular, as the courts have grown more skeptical of diagnostic patents, potential licensees and investors have become more cautious about investing to commercialize diagnostic technologies invented by Cleveland Clinic researchers.

Cleveland Clinic is one of the leading health care institutions in the world, frequently ranked as among the top five in the U.S. overall, the best in the nation in cardiology and heart surgery, and, recently, as second overall in the world.²² One aspect of this excellence is that its researchers and doctors consistently innovate to develop new therapies and new treatment methods to serve patients. In 2000, Cleveland Clinic Innovations was founded to help commercialize these innovations in order to bring them to market, and, ultimately, to patients.

One particular Cleveland Clinic innovation with great potential to help patients is a test to diagnose the risk for cardiovascular disease. The test is for an enzyme released by white blood cells, myeloperoxidase (MPO). Cleveland Clinic researchers discovered a method for testing for MPO that could be used as an indicator for cardiovascular disease. According to the Centers for Disease Control, “about 647,000 Americans die from heart disease each year — that’s 1 in every 4 deaths. Heart disease costs the United States about \$219 billion each year.”²³ Since cardiovascular disease is the leading cause of death in the U.S.,²⁴ a significant improvement in ability to predict it could greatly benefit public health.

Cleveland Clinic sought to bring this test to patients. It started by filing patent applications for its researchers’ MPO test in 2001 and received a patent in 2007. In 2009, it launched a spinoff to make the test commercially available. This company, Cleveland HeartLab, eventually employed 200 people in Northeast Ohio. It performs testing and manufactures tests for other labs and has already served many thousands of patients.

Unfortunately, Cleveland Clinic and its spinoff, Cleveland HeartLab, have encountered a frustrating legal environment, as the legal system has treated its patents unpredictably and inconsistently. Initially, its 2007 patent was re-examined twice by the USPTO and found valid. However, in 2015 Cleveland Clinic had to enforce its patents against True Health Diagnostics, a private equity-owned company. The District Court found three of Cleveland Clinic’s patents (including the 2007 patent) invalid under the Supreme Court’s *Mayo* and *Alice* decisions. Cleveland Clinic’s appeal was not successful.

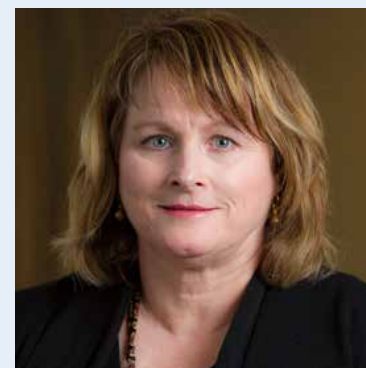
After the USPTO issued new examination guidelines that clarified what patent claims could be made under the *Mayo* and *Alice* framework, Cleveland Clinic returned to USPTO with new patent applications. In 2017, it successfully obtained new patents for methods for MPO testing that conformed to the new guidelines.

²² Centers for Disease Control and Prevention, Heart Disease Facts, <https://www.cdc.gov/heartdisease/facts.htm>

²³ Melonie Heron, Deaths: Leading causes for 2017, 68 National Vital Statistics Reports (2017).

²⁴ *Cleveland Clinic v. True Health Diagnostics*, (2018-1218, April 1, 2019).

Mary Kander General Manager of Technology Commercialization, Cleveland Clinic



KANDER

We interviewed Mary Kander, General Manager of Technology Commercialization at Cleveland Clinic. Ms. Kander provided further insight into the changing nature of licensing in the life sciences as the legal ground for patents has shifted. Ms. Kander shared her observations and experiences gained through her work at the Cleveland Clinic, but did not speak

on behalf of the Clinic, and her opinions and observations were her own. However, her observations echoed and complemented O’Neill’s statements of behalf of Cleveland Clinic.

Ms. Kander views the effect of changes to the patent system on the ability to deliver health innovation to patients from a unique and important vantage point as a commercialization manager at one of the world’s elite medical research institutions. She has spent 16 years with the Cleveland Clinic, working on commercialization.

Ms. Kander heads the group that does most of the Clinic’s licensing. She and her team are the bridge between life sciences researchers doing cutting-edge research and the life sciences businesses that translate that research into treatments for patients.

Before deciding to attempt to commercialize an innovation, Ms. Kander and her team evaluate its commercialization potential. Typically, this evaluation considers the potential market for an invention and whether it is patentable, or otherwise protectible with intellectual property rights. **“Without a patent, nobody will invest in drug development. It is also very important for medical devices. The cost of clinical trials alone would prevent it, plus the investment of time. People will not invest unless they know they have proprietary rights.”**

She observed that health information technology, where patents are less important, has become a bigger part of the portfolio. Ms. Kander says that the “trends are toward greater business opportunities in health IT.” This observation reflects larger trends in investment data discussed elsewhere in this paper: In recent years, there has been a relative shift in business investment overall toward health IT and software.

Ms. Kander further offered that given recent trends in patentability for software and the patent system generally, it is often “wiser to keep software as a trade secret” instead of seeking a patent. However, “on the non-IT side, investors are not going to fund a project where there are not patents.”

She says that recent changes to the patent system have affected the way in which her group, as well as potential licensees and investors, approach commercializing innovations. Unsurprisingly, given Cleveland Clinic’s challenges in the *Cleveland Clinic v. True*

Health Diagnostics cases, patentability issues regarding diagnostic tests have made her “more watchful regarding whether we are going to invest in biomarker.”

She sees potential licensees and investors as more cautious regarding diagnostics too. “There is a wariness in terms of licensing biomarkers for commercial opportunities.”

The potential impact of this caution is important. “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 patent eligibility of diagnostics is likely to harm the development of personalized medicine. **“The unavailability of diagnostic patents, or uncertainty regarding their validity, is likely to affect an important component of personalized medicine.”**

She does note that research continues, but the ability to license diagnostics and get them to patients is more challenging. “It is not impacting research, but it is impacting the ability to license.” “We still license, but we will not be licensing as much in the past.”

She also predicts that researchers may be less likely to share knowledge in some instances. “If a researcher publishes information about a diagnostic, they still have lab methods and knowhow that aren’t communicated in that paper.” Without the ability to patent the diagnostic, the incentives are greater to keep that related information confidential.

Uncertainty regarding patentability causes potential licensees to take a wait-and-see approach. “In the past, we could get interest from potential licensees once we filed a patent application and they could look at claims. Now it’s more typical that they want to wait to see if the patent issues.” This caution is “slowing the route to commercialization, as companies are more wary of licensing an unissued patent. Some will still do it, but it is much less frequent.”

This greater desire among licensees to wait for an issued patent combined with the first-to-file system is driving earlier patenting. There is now an incentive to file a patent application earlier, both to preserve the opportunity to patent and to persuade licensees.

However, earlier filing of patents does not fit well with the timeline of commercialization in the life sciences. Clinical trials are time consuming, and, other things being equal, licensees would prefer to wait to file to preserve patent term. Ms. Kander says that while licensees are more likely to wait for an issued patent, “they are losing time to develop a commercial treatment.” As a result, some of the same companies that are hesitant to license before patent issuance are also complaining that “you filed too early.”

When asked whether the government could step in to fund the commercialization of new technologies, she is skeptical. She observes that **“we get funding from the state of Ohio to help support some of our spinoffs, but even the state wants to see a patent first too. Everybody wants the certainty of a patent before they put their money at risk.”**

Soon, Cleveland Clinic was in litigation with True Health again, asserting these new patents. Once again, the District Court diverged from the USPTO and invalidated the patents. On appeal to the Federal Circuit, the court affirmed the District Court Decision. Notably, it declined to interpret patent eligibility consistently with the USPTO's guidelines, stating "[w]hile we greatly respect the PTO's expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance."²⁵

With the institutions that make up the U.S. patent system providing contradictory and unpredictable guidance, those who rely on the system to make investment decisions face much greater uncertainty and risk. Peter O'Neill, Executive Director of Cleveland Clinic Innovations, testified about the challenges before the Senate Judiciary IP Subcommittee in June 2019.

O'Neill observed that this "uncertainty has a very meaningful impact on our ability to develop and bring new advances to market for use with patients and consumers."²⁶ O'Neill continued: "These questions about patents hurt the ability of Cleveland Clinic Innovations and other innovators to bring new products to market that involve the life sciences."²⁷

According to O'Neill, this uncertainty negatively impacts every step of the commercialization process, as patent protection supports investment in every step. "Each of these steps took time and resources that were made possible only by the promise of return on investment enabled by patent protections."²⁸

First, the availability of a patent affects whether Cleveland Clinic attempts to commercialize an invention at all. "At Cleveland Clinic Innovations, we have an established process to assess inventions, based on their likelihood to be able to be developed into commercial products. Ability to get protectable intellectual property (usually in the form of a patent) is the first, and most influential factor in our assessment. If an invention can't get intellectual property protection, usually that is a fatal flaw and the invention is abandoned at that point."²⁹

Not only does it affect Cleveland Clinic's decision to attempt to commercialize, but it also affects the investment community's decision making. "The resources for [commercialization] generally come from outside of Cleveland Clinic Innovations, working with the investment community... The absence of that financial backing can make it nearly impossible to bring products to market."³⁰ O'Neill says investors watch the law closely, and it affects their decisions: "[F]inancial supporters are following federal court cases like ours, and weighing whether a patent is likely to withstand a court challenge."³¹

Much is at stake, as Cleveland Heart Lab is only one of dozens of technologies that Cleveland Clinic has put into spinoffs and one of hundreds of it has licensed "that have led to the creation of thousands of jobs and impacted countless patients. Patents and intellectual property were an essential part of all this work"³²

²⁵ Testimony of Peter O'Neill, Executive Director of Cleveland Clinic Innovations, to the Subcommittee on Intellectual Property of the Senate Judiciary Committee, June 11, 2019, available at <https://www.judiciary.senate.gov/imo/media/doc/O'Neill%20Testimony.pdf>

²⁶ Ibid.

²⁷ Ibid.

²⁸ Ibid.

²⁹ Ibid.

³⁰ Ibid.

³¹ Ibid.

³² Ibid.

Bibliography

Arnold, Brian G. et al, Patent Litigation Trends in The Wake of TC Heartland (April 25, 2019), IP Address, <https://lewisbrisbois.com/blog/category/intellectual-property-technology/patent-litigation-trends-in-the-wake-of-tc-heartland>

European Patent Office & European Union Intellectual Property Office, High-growth firms and intellectual property rights: IPR profile of high-potential SMEs in Europe, May 2019, [http://documents.epo.org/projects/babylon/eponet.nsf/0/F59459A1E64B62F3C12583FC002FBD93/\\$FILE/high_growth_firms_study_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/F59459A1E64B62F3C12583FC002FBD93/$FILE/high_growth_firms_study_en.pdf)

European Patent Office & European Union Intellectual Property Office, Intellectual property rights intensive industries and economic performance in the European Union (May 2019). <https://www.epo.org/service-support/publications.html?pubid=201#tab3>

Farre-Mensa, Joan and Hegde, Deepak and Ljungqvist, Alexander, What Is a Patent Worth? Evidence from the U.S. Patent 'Lottery' (June 25, 2019). Journal of Finance, Forthcoming; USPTO Economic Working Paper 2015-5. Available at SSRN: <https://ssrn.com/abstract=2704028> or <http://dx.doi.org/10.2139/ssrn.2704028>

Gornall, Will and Strebulaev, Ilya A., The Economic Impact of Venture Capital: Evidence from Public Companies (November 1, 2015). Stanford University Graduate School of Business Research Paper No. 15-55. Available at SSRN: <https://ssrn.com/abstract=2681841> or <http://dx.doi.org/10.2139/ssrn.2681841>

Graham, SJH, Grim, C, Islam, T, Marco, AC, Miranda, J. Business dynamics of innovating firms: Linking U.S. patents with administrative data on workers and firms (2018). J Econ Manage Strat. 27: 372– 402. <https://doi.org/10.1111/jems.12260>

Holte, Ryan T., The Misinterpretation of eBay v. MercExchange and Why: An Analysis of the Case History, Precedent, and Parties (2015). Chapman Law Review 18: 677.

IAM Media, IAM Annual IP Benchmarking Survey (2018). IAM Magazine, Issue 90.

Pitchbook-NVCA Venture Monitor Q4 (2019), available at <https://pitchbook.com/news/reports>.

Silicon Valley Institute for Regional Studies, 2020 Silicon Valley Index, <https://jointventure.org/news-and-media/news-releases/1900-2020-silicon-valley-index-continued-expansion-mounting-challenges>.

Taylor, David O., Patent Eligibility and Investment (February 24, 2019). Cardozo Law Review, Forthcoming; SMU Dedman School of Law Legal Studies Research Paper No. 414. Available at SSRN: <https://ssrn.com/abstract=3340937> or <http://dx.doi.org/10.2139/ssrn.3340937>

USPTO, Intellectual Property and the U.S. Economy: Industries in Focus (2012). <https://www.uspto.gov/learning-and-resources/ip-motion/intellectual-property-and-us-economy>

USPTO, Intellectual Property and the U.S. Economy 2016 Update. <https://www.uspto.gov/sites/default/files/documents/IPandtheUSEconomySept2016.pdf>

Wu, J. John, Why U.S. Business R&D Is Not as Strong as It Appears (June 2018). Information Technology & Innovation Foundation, <http://www2.itif.org/2018-us-business-rd.pdf>

Appendix: Methodology

The objective of this study was to determine trends in venture capital investment in entrepreneurial startups during the last 15 years, a period of tremendous change for the patent system.

The motivation for examining these trends was the claim that venture capital investment was shifting away from patent-intensive industries. Some data exists to support this contention, particularly survey results from a study by Professor David Taylor, where he interviewed ___ venture capitalists regarding their firms' responses to changes in the law of patent eligibility. However, direct data about venture capital investment in specific type of firms was still lacking. It was known that since the Great Recession, aggregate venture capital investment has been growing along with the economy. This fact made it difficult to determine what, if anything, had changed about venture capital investment in patent-intensive industries, absent industry-specific data.

With the help of the Alliance of U.S. Startups & Inventors for Jobs (USIJ), we obtained data from Pitchbook. Pitchbook is a financial data company that tracks data regarding venture capital and private and public equity markets. Its database, described further below, tracks aggregate annual venture capital investment in the U.S., classifying it into many detailed industry categories. The data enabled us to gain greater clarity regarding investment trends in recent year.

We supplemented the quantitative data from Pitchbook with a qualitative study comprised of innovators and investors with a long and continuing record of success in entrepreneurial startups, particularly in the life sciences. The case studies provided insights into potential motivations underlying the trends in the data.

The Data

We obtained the data regarding venture capital investment from Pitchbook. Pitchbooks aims to compile the most comprehensive database of venture capital deals possible. It describes a data collection processes that uses “[m]ore than 650,000 web crawlers [to] scan the internet—capturing relevant financial information from news articles, regulatory filings, websites, press releases and more.”³² It then uses “natural language processing and machine learning technology” to process and organize the information. Its team then verifies the information through a variety of processes, including individual communication.³³ Pitchbook uses this data to provide various subscription services, public reports, and other products and intelligence.

The data we obtained from Pitchbook contains aggregate numbers of deals and money invested in various industry sectors for 2004 through 2017. Specifically, it includes, to the best Pitchbook can determine from its sources:

- The total amount of venture capital dollars invested in the U.S. each year
- The total number of venture capital deals done in the U.S. each year
- The total number of companies funded by venture capital money in the U.S. each year (a number slightly smaller than deals, since some companies receive more than one round of funding deal a given year)
- Each of the above numbers, broken down, by industry category. Pitchbook uses its own unique identification of industry, breaking them down into over 200 categories.

Further information regarding the Pitchbook methodology, as well as its description of its industry categories is published in the quarterly Pitchbook-NVCA Venture Monitor.³⁴

Determining Trends in VC Investing

To determine trends in venture capital investment in particular industries, we normalized the data to show investment in a particular sector as a percentage, or share, of overall investment for the year. This transformation is necessary to account for economic growth and inflation. Venture capital investment is affected by those wider economic trends, as well as by endogenous factors. Therefore, it is most useful to understand VC investment in patent-intensive industries as a share of companies funded and total money invested. We therefore calculated the proportion of money or deals going to a particular industry as a percentage of all activity for the year, rather than using absolute numbers.

Determining Which Industries are Patent-Intensive

While there is much conventional wisdom regarding which industries most rely on patents, determining patent intensity with consistency and credibility is challenging. Fortunately, the USPTO pioneered a methodology in its 2012 report, *Intellectual Property and the U.S. Economy: Industries in Focus*,³⁵ which determines patent intensity based on the number of patents per job.

It further describes its methodology as follows:

We calculated a measure of industry patent “intensity,” defined as the ratio of total patents over the five years in a NAICS category to the average payroll employment by industry. Because employment is a gauge of industry size, dividing patent counts by employment normalizes patenting activity with respect to industry size. This approach helps put all industries on an even playing field, so that the most patent-intensive industries were defined not as the ones with the most patents, but rather those with the most patents per job.³⁶

The USPTO relies on a concordance between patent classifications and NAICS codes it developed earlier.³⁷ Each patent is classified by industry based on the final use of the invention in the economy. (This choice excludes the inherently patent-intensive R&D and licensing firms from its classification, unlike the European Patent Office study described on next page).

³² Pitchbook, Research Process <https://pitchbook.com/research-process>.

³³ Ibid.

³⁴ See Pitchbook-NVCA Venture Monitor Q4 (2019), available at <https://pitchbook.com/news/reports>.

³⁵ USPTO, *Intellectual Property and the U.S. Economy: Industries in Focus* (2012), available at https://www.uspto.gov/sites/default/files/news/publications/IP_Report_March_2012.pdf

³⁶ Ibid at 6.

³⁷ Ibid at 5.

One key limitation of the USPTO's classification of patent-intensive industries is that it applies to the manufacturing industries only. It is thus an indicator for patent-intensive manufacturing industries. This choice was based on a few reasons. First, the USPTO NAICS-patent classification concordance was developed only for the manufacturing industries. Second, the USPTO desired to avoid several methodological difficulties with comparing outputs and employment in manufacturing vs services industries. Third, it also reflects the conventional wisdom that manufacturing is more patent-intensive than other industries.

A key further point, however, is that the USPTO defines manufacturing broadly to include the pharmaceutical and biotech industries.

The USPTO determines which manufacturing industries are patent intensive by taking its list of manufacturing industries, finding the mean, and classifying all patent intensive industries with above-the-mean patent/job counts as "patent-intensive." The USPTO updated its report in 2016, and we rely on its list of patent-intensive industries from that report.³⁸



Classification of Patent-Intensity for Manufacturing Industries 2009–2013 USPTO <i>Intellectual Property and the U.S. Economy: 2016 Update</i>	
Patent-Intensive <i>(above mean patents/1000 jobs)</i>	Non-Patent-Intensive <i>(below mean patents/1000 jobs)</i>
Computer and peripheral equipment Communications equipment Other computer and electronic products Navigational, measuring, electromedical, and control Instruments Semiconductors and other electronic components Basic chemicals Other miscellaneous Electrical equipment, appliances, and components Medical equipment and supplies Pharmaceutical and medicines Other chemical product and preparation Machinery	Plastics and rubber products Fabricated metal products Other transportation equipment Motor vehicles, trailers and parts Nonmetallic mineral products Textiles, apparel and leather Aerospace product and parts Furniture and related products Primary metal Wood products Paper, printing and support activities Beverage and tobacco products Food

³⁸ USPTO, *Intellectual Property and the U.S. Economy: 2016 Update* 33 (2016).

We decided that it would also be useful to examine investment trends in the industries that the USPTO left out of its calculations by focusing exclusively on manufacturing industries. While it is useful to examine the most patent-intensive manufacturing industries, conventional wisdom and other evidence indicates that all of the manufacturing industries, including the ones designated by the USPTO as non-patent-intensive, rely on patents more than other sectors, such as services and software.

Fortunately, other studies conducted since the USPTO developed its patent-intensive classification examine the economy more broadly. First, Graham (2018) used U.S. patent and US Census data to construct a longitudinal database tracking inventors and patent owning firms over time from 2000 – 2011, matching patent grants to firms. Among other things, that study confirmed the conventional wisdom that manufacturing firms are more likely to obtain patents via grant or assignment than firms in other sectors.

Second, the EUIPO conducted a study that measured patent-intensity across all industries. The results largely confirm that manufacturing industries are the most patent-intensive, with a few exceptions. Like the USPTO, the EUIPO classified all industries above the mean for its patent intensity indicator as patent-intensive industries.

Unlike the USPTO, the EUIPO was averaging far more industries, so its set of patent-intensive industries is larger. Also, it used more refined subcategories than the USPTO, and used the NACE system for classifying industries. Here are a few key findings:

- Of the EUIPO patent-intensive industries, over 81% of them (in terms of categories) are in the manufacturing sector.
- The EUIPO, unlike the USPTO, designated a category of industries as industries performing IP licensing or R&D (NACE Sectors 72, 74, and 77). Unsurprisingly, these industries were the most-patent intensive.
- Mining and Natural Resource Extraction was also patent-intensive, a fact which has been observed elsewhere, including Graham (2018).
- Software publishing (other than games) makes it onto the EUIPO's list of patent-intensive industries, but it is, on average, the least patent-intensive of the EUIPO's patent intensive industries. In other words, it falls just above the mean patent-intensity for all industries.
- The EUIPO's top 20 most patent-intensive industries largely correspond to the USPTO's patent-intensive manufacturing industries. (The correspondence is not complete, as the EUIPO uses a different industry code system — NACE as opposed to NAICS and broke them down to a more granular level). The exceptions to the similarity are the IP licensing industries and the natural gas extraction sector.



EUIPO Top 20 Most Patent-Intensive Industries

Sector	NACE Codes	Number of Industries	Percent of Categories	Average Intensity
Mining, Natural Resource Extraction, & Support	Sectors 6, 7 & 9	4	3%	3.20
Manufacturing & Processing	Sectors 10, 12, 13, 14, 17, 20-32	114	81%	4.73
Repair & Installation of Equipment	Sector 33	2	1%	1.00
Distribution & Sales	Sectors 35 & 36	9	6%	1.04
Other Software Publishing (software other than games)	Sector 58	1	1%	1.91
Telecommunications Activities	Sector 61	3	2%	2.22
Engineering activities, related technical consulting, and technical testing	Sector 71	2	1%	1.18
IP licensing (other than ©); Research & development	Sectors 72, 74, 77	5	4%	19.87

We decided that it would also be useful to examine investment trends in the industries that the USPTO left out of its calculations by focusing exclusively on manufacturing industries. While it is useful to examine the most patent-intensive manufacturing industries, conventional wisdom and other evidence indicates that all of the manufacturing industries, including the ones designated by the USPTO as non-patent-intensive, rely on patents more than other sectors, such as services and software.

Fortunately, other studies conducted since the USPTO developed its patent-intensive classification examine the economy more broadly. First, Graham (2018) used U.S. patent and US Census data to construct a longitudinal database tracking inventors and patent owning firms over time from 2000 – 2011, matching patent grants to firms. Among other things, that study confirmed the conventional wisdom that manufacturing firms are more likely to obtain patents via grant or assignment than firms in other sectors.

Second, the EUIPO conducted a study that measured patent-intensity across all industries. The results largely confirm that manufacturing industries are the most patent-intensive, with a few exceptions. Like the USPTO, the EUIPO classified all industries above the mean for its patent intensity indicator as patent-intensive industries.

Unlike the USPTO, the EUIPO was averaging far more industries, so its set of patent-intensive industries is larger. Also, it used more refined subcategories than the USPTO, and used the NACE system for classifying industries. Here are a few key findings:

- Of the EUIPO patent-intensive industries, over 81% of them (in terms of categories) are in the manufacturing sector.
- The EUIPO, unlike the USPTO, designated a category of industries as industries performing IP licensing or R&D (NACE Sectors 72, 74, and 77). Unsurprisingly, these industries were the most-patent intensive.
- Mining and Natural Resource Extraction was also patent-intensive, a fact which has been observed elsewhere, including Graham (2018).
- Software publishing (other than games) makes it onto the EUIPO's list of patent-intensive industries, but it is, on average, the least patent-intensive of the EUIPO's patent intensive industries. In other words, it falls just above the mean patent-intensity for all industries.
- The EUIPO's top 20 most patent-intensive industries largely correspond to the USPTO's patent-intensive manufacturing industries. (The correspondence is not complete, as the EUIPO uses a different industry code system — NACE as opposed to NAICS and broke them down to a more granular level). The exceptions to the similarity are the IP licensing industries and the natural gas extraction sector.



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

