Testimony
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Statement Before the House Committee on Small Business

Intellectual Property 101: How Small Business Owners Can Utilize Intellectual Property Protections in Their Businesses

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Hon Steve Chabot. Chairman Hon Nydia M. Velazquez. Ranking Member



Good morning. I want to thank you Chairman Chabot, ranking Member Velazquez and Members of the Committee for this opportunity to speak with you today about the juxtaposition of intellectual property and small and startup businesses. One of the hallmarks of these businesses is that they often have aspirations to be larger ones, with economic and social impact that are the backbone of job creation, economic independence, and prosperity.

Great ideas are ones that solve problems. Protecting those ideas so they can mature for the benefit of others is key, when we consider the growth, and scalability of small and startup businesses. The protection of ideas, designs, and innovation takes many forms, including patents, trademarks, and copyrights. The existence of patents and intellectual property was a vision held by our forefathers and they created those IP rights under our constitution.

I am the founder and CEO of a company called Curemark in Rye, NY. Curemark is currently working on an enzyme replacement drug for autism. The company was founded in 2007, but I personally have been working on the science since 1998. As a company we have conducted two FDA phase three clinical trials across the US at 33 clinical sites. We plan to meet with FDA later this year to discuss our findings and to file a New Drug Application.

Curemark, like almost all other startups has transitioned through a process of discovery, validation, and scale. We would not exist as a company, we would not have the opportunity to work on this drug treatment if it were not for our intellectual property protection. Our IP forms the basis of our company. It has allowed us to protect our findings, raise money, demonstrate efficacy, and put forth the novel science which hopefully will benefit millions of American children. Curemark and its wholly owned subsidiary has made discoveries and filed corresponding patent applications resulting in 120 issued US and Foreign Patents, along with an additional 80 Patents Currently Pending.

Curemark, since inception, recognized not only the need to patent its discoveries but to develop and execute on a well-rounded IP strategy. The extraordinary length of time pharmaceuticals require to develop, become validated through benchtop testing and human clinical trials, obtain regulatory approvals, and bring to a drug market requires the creation of an environment for relentless discovery and innovation. US and Foreign Patent Terms, FDA and Foreign Regulatory Protections including patent Term Extensions, and new related discoveries resulting in patents are critical elements of our IP strategy.

My initial Autism research resulted in the discovery of low levels of specific enzymes in Autistic Children. The resulting biomarker patent that ensued was fundamental in the founding of Curemark and certainly helped with subsequent funding. Throughout the development of our first indication and subsequent clinical trials we have made a myriad of discoveries related to the treatment of Autism and Autism Spectrum Disorders, along with various other neurological diseases such as ADHD, Parkinson's, Schizophrenia and Addiction.

Galenagen, our wholly owned subsidiary research corporation has created additional discoveries related to treatments for E. Coli, Staphylococcus Aureus infections and wound healing. Galenagen currently has 47 issued US and Foreign Patents, with an additional 30 patents pending.

Patents grow value at all stages in a company's lifecycle. They are especially critical for risk mitigation in startups that originate in every field of endeavor. Patents inherently validate discoveries and afford Early Investors' confidence in funding a startup company, especially when extensive due diligence for small investments would otherwise not be economically viable. Patents afford a sustainable competitive advantage, allow for licensing and joint ventures, and are often critical in obtaining funding at all stages of a company's growth.

The issuance of a patent is in my opinion one of the most egalitarian processes that exists in our country. Patents are granted without regard for race, age, gender, socioeconomics, education, geography, or even living status (Yes, even a deceased person can be granted a patent if the heirs apply for one).

In the early days of our republic women in did not share in equal rights with men to own property, to vote or to a separate economy. Despite this inability for women to own, commercialize or to receive value from their patents they still could be granted one, thus rewarding their innovation and creativity equally despite the presence of COVERTURE. A patent therefore promoted in theory equal economic status to an idea or invention regardless of gender. ¹

Today, there remains a significant dearth of women patent holders. Recent statistics from the *Institute for Women's Policy Research* shows that 18.8% of all patents list at least one woman as an inventor but only 7.7% list a woman as the primary inventor.²

The National Bureau of Economic Research makes the case that if the patenting gap were closed just between men and women it would result in an increase in GDP of 2.7%. A 2.7% increase in per capita GDP could dramatically change our trade deficit, quality of life and the overall world economy.³

While we so often attribute this patenting gap to a lack of women in STEM, Hunt et.al argue that this fact only explains a portion of this gap. Using data from

¹ Fallon, Joan. *Is the Lack of Women Patent Holders Hurting the US Economy*? 2017 MoneyInc. http://moneyinc.com/lack-women-patent-holders-hurting-us-economy/

² Milli, Jessica et.al.2016 *The Gender Patenting Gap* Institute for Women's Policy Research. https://iwpr.org/wpcontent/uploads/wpallimport/files/iwpr-export/publications/C441%20(2).pdf

³ Hunt, Jennifer, Jean-Philippe Garant, Hannah Herman, and David J. Munroe. 2012. *Why Don't Women Patent?* National Bureau of Economic Research. http://www.nber.org/papers/w17888.pdf>.

the 2003 National Survey of College Graduates (NSCG), collected under the auspices of the National Science Foundation, they examine both the numbers of patents granted to men and women and the number of licensed or sold patents (commercialized) by gender and degree. ⁴

They conclude that women are much less likely to be granted a patent than men, and are somewhat less likely to commercialize or license the patents they are granted. Because women with a degree in STEM (they use S&E in lieu of STEM) patent little more than other women, increasing the share of women in S&E would not greatly increase patenting. They also conclude that increasing the number of women with S&E would account for only 7% of the gender gap in commercialized patents. They further conclude and herein lies the key – that the greatest disparity, 78%, is due to the patenting gap among holders of S&E degrees.

Further the research shows that there is a racial and socioeconomic patenting disparity as well, where children in the top 1% of income distribution are 10 times more likely to be inventors than children with below median income parents. We also know that children exposed to innovation are more likely to be inventors, and where they live influences that exposure. ⁵

A 2013 Brookings institute report stated that the 100 largest metro areas represents 65% of the us population but they represent 80% of the inventors granted patents since 1976. growing to 82% since 2005. While metro locations appear to drive patenting, the need for innovation and patents exists in rural and manufacturing communities. The report shows that the patenting effect is actually larger than the

⁴ ibid

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⁵Lindquist, M, J. Sol, and M.Van Praag (2015) Why Do Entrepreneurial Parents Have Entrepreneurial Children? *Journal of Labor Economics* 33(2), 269-296

attainment of a bachelor's degree attainment. So, education level alone is not the driver of innovation. ⁶

The US Chamber of Commerce Global Intellectual Property Center newest report entitled: *Employing Innovation Across America*, found that in "IP-intensive industries, workers make, on average, higher wages than their private sector counterparts. Additionally, IP drives each state's manufacturing exports, leads to increased R&D investment, and stimulates and protects innovation". ⁷

In conclusion, I would like to state that intellectual property belongs to all Americans. Innovation is a foundational principle of our great nation, and every state and local jurisdiction in this country plays a role. Genius is equally distributed throughout this country, providing equal access to the patent process can foster innovation.

I believe that the federal government is key in fostering this innovation.

A nationwide awareness campaign at the local level with every state participating can begin the conversation. Setting up federal OFFICES OF INNOVATION in every state thus making the patent process accessible to everyone will go a long way in outreach.

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⁶ Rothwell, Jonathan, Lobo, José, Strumsky, Deborah and Muro, Mark. 2013. *Patenting Prosperity: Invention and Economic Performance in the United States and its Metropolitan Areas*. Bookings Institute. https://www.brookings.edu/wp-content/uploads/2016/06/patenting-prosperity-rothwell.pdf

⁷ Noyes, Brian. 2015. *Employing Innovation Across America-Being Competitive in the Global Marketplace*. Global Innovation Policy Center. US Chamber of Commerce. http://www.theglobalipcenter.com/employing-innovation-across-america-being-competitive-in-the-global-marketplace/

We need to encourage innovation in our young people nationwide regardless of whether they have an idea for a new block chain technology, a new type of screwdriver, a new method for growing corn, or a car that runs on water. Innovation is race, color socioeconomics, geography and gender blind. It needs to be fostered in our young people taught in our schools, and beyond. The USPTO, the SBA and the US Congress form a powerful platform from which patents can become a part everyone's awareness, and together we can change the face of our nation through our innovation.

Thank you again for giving me the chance to speak with you. I look forward to your questions.