

DRIVING AMERICAN INNOVATION: CREATING JOBS AND BOOSTING OUR ECONOMY

HEARING BEFORE THE SUBCOMMITTEE ON INTELLECTUAL PROPERTY, COMPETITION, AND THE INTERNET OF THE COMMITTEE ON THE JUDICIARY HOUSE OF REPRESENTATIVES ONE HUNDRED TWELFTH CONGRESS FIRST SESSION

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DRIVING AMERICAN INNOVATION: CREATING JOBS AND BOOSTING OUR ECONOMY

WEDNESDAY, MARCH 9, 2011

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON INTELLECTUAL PROPERTY,
COMPETITION, AND THE INTERNET,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:05 a.m., in room 2141, Rayburn Office Building, the Honorable Bob Goodlatte (Chairman of the Subcommittee) presiding.

Present: Representatives Goodlatte, Coble, Sensenbrenner, Chabot, Poe, Chaffetz, Reed, Marino, Adams, Quayle, Watt, Conyers, Berman, Chu, Deutch, Wasserman Schultz, and Jackson Lee.

Staff present: (Majority) Vishal Amin, Counsel; Olivia Lee, Clerk; and Stephanie Moore, Minority Counsel.

Mr. GOODLATTE. Good morning. This hearing of the Subcommittee on Intellectual Property, Competition, and the Internet will come to order.

Given the subject of this hearing, I think it is noteworthy that we mention that the United States Senate passed the patent reform bill by a vote of 95 to 5 yesterday. So we will look forward to introduction of a House bill and action on this side of the Capitol very soon.

This hearing is on driving American innovation, creating jobs, and growing the economy.

I will recognize myself for an opening statement.

The American experience has been shaped not just by who we are but by the things that we have done, and as a Nation, we have accomplished a lot. America owes much to the genius of inventors like Thomas Edison, the Wright Brothers, Alexander Graham Bell, Samuel Morse, and many of the Nation's Founding Fathers. Indeed, many of our Nation's Founders were also inventors and authors. Perhaps that is one of the reasons they had the incredible foresight to include protections for intellectual property in the U.S. Constitution.

Article I, section 8 of our Constitution lays the framework for our Nation's patent and copyright laws. It grants Congress the power to award inventors and creators for limited amounts of time exclusive rights to their inventions and works. The Founders realized that this type of incentive was crucial to ensure that America would become the world's leader in innovation and creativity.

Almost 225 years later, this incentive is still producing dramatic results for our Nation. The American innovative spirit continues to thrive based on our Nation's strong intellectual property laws. We are seeing entirely new industries and economic sectors springing to life from high technology to biotech to aerospace and defense.

It is true that our Nation is weathering a very difficult storm right now, one that has left many people out of work and has stalled business development. Our goals need to be squarely focused on reducing unemployment, helping get businesses growing again, and moving our economy back into gear.

I believe American innovation and creativity will lead us out of this storm and back to strong economic growth. However, to encourage this result, it is crucial that we have strong and effective laws in place that protect inventions and creative works. This will send the message that innovators can feel secure in dedicating precious resources to a new product or idea. It will also continue to bring predictability to the values of intellectual property which will, in turn, encourage banks, venture capitalists, and others to invest in America's ideas.

Today's hearing, "Driving American Innovation: Creating Jobs and Boosting Our Economy," will focus on how our Nation's intellectual property laws encourage innovation and how innovation then creates jobs and spurs our economy. In addition, this hearing will show how intellectual property plays such a strong role in our daily lives, from advancing education and health care to helping keep us safe and improving the lives of people throughout the globe through science and technology. This showcase hearing will also be an opportunity for us to see and hear about some of the latest and exciting inventions and innovations being developed by our witnesses, which I am really looking forward to.

One is an exciting new idea of science called "regenerative medicine" that seems to verge on science fiction but is indeed a reality. Technologies are being developed that can create organs and tissues using 3D printing technology, and in the near future, we may even see these technologies help in the regeneration of actual limbs. This groundbreaking work is also being done in partnership with the U.S. military through the Armed Forces Institute for Regenerative Medicine established under President Bush, known as AFIRM. AFIRM is a partnership between universities and the Defense Department that is yielding real-world benefits to both our wounded warriors and civilian patients.

We are also pleased to have Rosetta Stone here, a Virginia-based company which started in a seed warehouse in my district whose story embodies the American dream. Having gone from a small start-up to a global success, they now bring their educational software to individual students and teachers, the military, and our diplomatic corps around the world.

And finally, we have the Mechanical Engineering Department chair from the University of North Carolina at Charlotte. He is an inventor and holds several patents and has begun the process of commercializing his inventions through his own start-up company.

By highlighting the real-world implications of IP and innovation outside the legislative arena, we will see these issues come to life

and demonstrate the tangible link between invention and job creation.

In addition, we will see that inventors and businesses in all stages of development rely on strong intellectual property laws to succeed.

I look forward to hearing from our distinguished panel today. They represent a variety of perspectives and industries, and I look forward to working with my fellow colleagues and the stakeholder community as we work to ensure that America's innovative industries remain strong and vibrant.

It is now my pleasure to recognize the Ranking Member, the gentleman from North Carolina, Mr. Watt?

Mr. WATT. Thank you, Mr. Chairman.

I want to rush to our witnesses to hear what they have to say, so I will be brief.

Over the past few hearings, we have heard about the connection between innovation and American job growth. Innovation in businesses with path-breaking technology and high growth potential can jump start the economy, make America more competitive, and accelerate job creation.

Public/private partnerships with universities all across the country advance revolutionary research and development efforts. Copyrights, patents, trademarks, industrial design rights, trade secrets, and other forms of intellectual property incentivize America's inventors and facilitate the commercialization of their talent which in turn results in substantial benefit to society.

Greater and deserved recognition of the importance of these intangible assets to our country's future has increased over the past months, with this Administration shining the spotlight on intellectual property-intensive industries and education. This is a unique moment in time to leverage this opportunity to sustain and build upon America's role in the global economy.

Today's witnesses are examples of the ingenuity and creativity that will keep us moving forward. I am happy to say that two of them—not only one of them—two of them—are from my congressional district, and I have had the pleasure of working with and knowing both of them. Dr. Smith, welcome. Dr. Atala—I have been in his laboratory—made an ear. So I can attest to how cutting edge what he will be talking about is today. So I am looking forward to their testimony and I welcome all of the witnesses.

I will yield back the balance of my time. I think Mr. Conyers wanted to make a statement too.

Mr. GOODLATTE. I thank the gentleman.

Yes. It is my pleasure to recognize the Ranking Member of the full Committee, the gentleman from Michigan, Mr. Conyers?

Mr. CONYERS. Thank you, Chairman Bob Goodlatte, Ranking Member Mel Watt.

This is a hearing that I can fully embrace and endorse. I want to congratulate the new leaders of the Committee because we all start out with the premise and agreement that innovation creates jobs and boosts the economy. And I think this gets us off to a very good start. The whole idea of regenerative—what Dr. Fulkerson will be talking about is extremely important. And I have talked to some doctors about this before the hearing. I do not know if you

know Dr. Samuel Epstein or the Physicians for a National Health Plan in Chicago, Dr. Clinton Young. They all are enthusiastic about it.

Now, Rosetta Stone is, of course, by their own admission the most popular learning process for languages. What I think may be important to the Committee this morning is how do we get immigrants into English fast and easy. Watt and I are studying Spanish at a furious rate. You will not know which is our first language pretty soon. We will become so articulate.

And, of course, we welcome Dr. Smith for where we are going.

Now, here is the challenge that the Committee faces. We have an intellectual property office—how long does it take to process? Years. So we are going to hear a lot of good things this morning, but behind the scenes—I hope it will be brought out in our discussion—we have got to get the office—all this innovation and wonderful inventions are really going to be on a totally different track from reality because it takes up to years to get anything through. And that is why I applauded the creation of this kind of subcommittee so that we can really focus in on that.

Then, of course, now we have a lot of the issues from the Senate side coming in. We have a lot of work to do.

Now, there are two things that we can do here, and we will appreciate your guidance. One, we can ratify the Senate bill and say, hey, let us move it on. Let us get going. But I am not so sure because locked up in that are some huge issues around “first to file” and other things that I think have to be carefully examined.

Now, all those who have been following the Senate and their actions on the patent bill, fine. This is one Member that has not had that opportunity, and I think all these issues converge at the hearing this morning.

So, Chairman Goodlatte, I congratulate you and the Ranking Member again, and I look forward to a great hearing.

Mr. GOODLATTE. Well, I thank the gentleman, and I can assure you that we will work in a bipartisan fashion to construct our own patent reform legislation and certainly appreciate what the Senate has done, but do our own thing even without the benefit of 3D printing technology or some other new invention that would make the Congress more efficient in creating legislation.

It is now my pleasure to introduce our very distinguished panel of witnesses. Each of the witnesses’ written statements will be entered into the record in its entirety, and I ask each witness to summarize their testimony in 5 minutes or less. To help you stay within that time, there is a timing light on your table, and when the light switches from green to yellow, you will have 1 minute to conclude your testimony. When the light turns red, it signals that the witness’ 5 minutes have expired.

And before I introduce each of you, I would like you to stand and be sworn.

[Witnesses sworn.]

Mr. GOODLATTE. Thank you very much and be seated.

Our first witness is Dr. Anthony Atala, Director of the Wake Forest Institute for Regenerative Medicine and the W.H. Boyce Professor and Chair of the Wake Forest University Medical School’s Department of Urology. Dr. Atala is an internationally recognized

expert in tissue engineering and through his research, he has applied for or received over 200 national and international patents and helped create several spinoff companies. Dr. Atala heads a team of over 270 physicians and researchers, and in 2007 his work was ranked as one of Time Magazine's top 10 medical breakthroughs of the year.

Dr. Atala has successfully created fully functioning bladders in the lab from patient's cells, and his team is currently working on regrowing over 30 other organs and tissues, including the liver, bone, corneas, heart, and kidneys. His team is developing new technology that can print human tissue on demand, and at last week's TED conference, it was reported that Dr. Atala literally printed a fresh kidney on stage.

Dr. Atala received his bachelor of arts from the University of Miami and his M.D. from the University of Louisville School of Medicine and did his fellowship at Harvard Medical School.

Our next witness is Dr. Michael Fulkerson, the chief technology officer of Rosetta Stone. Rosetta Stone, founded in 1992 as a family business in Harrisonburg, Virginia is now a global software company that currently employs about 2,000 people. Dr. Fulkerson is in charge of developing Rosetta Stone's innovative products and solutions to help people unlock their natural language learning ability. Previously he headed the company's advanced research and development group which was tasked with developing Rosetta Stone's future products. He started his career as a surface warfare officer in the United States Navy.

Dr. Fulkerson received his doctorate in computer science from Duke University where he did his dissertation work on techniques for building voice-enabled software systems. He received his bachelor's and master's degrees in computer science from Villanova University.

And I yield to the gentleman from North Carolina to introduce our third witness.

Mr. WATT. Thank you, Mr. Chairman.

I want to welcome the Duke graduate and the Wake Forest—

Mr. GOODLATTE. Now you are claiming all three. [Laughter.]

Mr. WATT. I am claiming all three of them today. So, hey, I am doing all right.

Mr. GOODLATTE. You will recognize the bipartisanship on this Committee.

Mr. WATT. Part of Wake Forest University is in my congressional district and all of the Center for Regenerative Medicine is in my district.

But I am here to introduce Dr. Scott Smith who is presently the professor and chair of mechanical engineering and engineering science at the University of North Carolina at Charlotte, which is also in my district.

Dr. Smith received his B.S. degree in mechanical engineering from Tennessee Technological University and his master's degree and Ph.D. from the University of Florida. His research areas include high-speed machining, process optimization, and machine dynamics.

Dr. Smith joined the faculty at the University of North Carolina at Charlotte in 1997 and became the deputy director of the Center

for Precision Metrology. He assumed the role of department chair in July of 2009. He is a member of a number of prestigious organizations and has co-authored the book "Machining Dynamics: Frequency Response to Improved Productivity."

He has a distinguished career, having received several awards. Most recently he became the recipient of the 2010 Research and Development 100 Award. He holds five patents and has served as a consultant to a variety of companies and organizations, including Alcoa, Apple, Bell Helicopter, Boeing, Caterpillar, and General Motors. The list goes on and on.

So we welcome you and look forward to each of your testimonies.

Mr. GOODLATTE. I thank the gentleman.

Mr. CONYERS. Mr. Chairman?

Mr. GOODLATTE. Yes?

Mr. CONYERS. Before we begin, could I recommend that we hold a hearing in North Carolina so that it would save us a lot of money. [Laughter.]

Mr. GOODLATTE. Maybe right on the border between Virginia and North Carolina.

Mr. CONYERS. All right.

Mr. GOODLATTE. I thank the gentleman for his suggestion.

We will turn now to Dr. Atala. Welcome.

TESTIMONY OF ANTHONY ATALA, M.D., DIRECTOR, WAKE FOREST INSTITUTE FOR REGENERATIVE MEDICINE, W.H. BOYCE PROFESSOR AND CHAIR, DEPARTMENT OF UROLOGY, WAKE FOREST UNIVERSITY SCHOOL OF MEDICINE

Dr. ATALA. Thank you, Chairman Goodlatte, Ranking Member Watt, Vice Chairman Coble, and Members of the Committee. It is a pleasure to be here to talk to you today about the field of regenerative medicine.

Regenerative medicine is basically a field that aims to replace or repair damaged tissues and organs in the body. It is actually a field that uses three different areas. You can actually use either biomaterials alone or small molecules to actually regenerate your body's own organs at the time of healing, or we can actually use cells for therapy, or we can actually use cells and biomaterials together to try to engineer tissues and organs for your body.

I do work at the Wake Forest Institute for Regenerative Medicine, a center that actually involves the work of about 300 scientists, all working together to bring these technologies from the bench to the bedside.

In our area, inventions and disclosures are extremely important, as you can imagine. We actually over the last 7 years have submitted or filed over 260 invention or patent applications from our team.

We at the institute work in over 30 different types of tissues and organs. We also are part of the Armed Forces Institute for Regenerative Medicine, a partnership that was built between Government and academia to actually try to overcome some of the challenges of organ disease and injury by focusing on basically five specific areas: burns, craniofacial injuries, limb and digit injuries, accelerating wound healing, and another injury that is called com-

partment syndrome that occurs when tissues are actually compressed and lead to tissue loss.

What are the potential benefits of regenerative medicine? I would like to define for you four benefits of the field of regenerative medicine.

The first one is basically the one which is most obvious which is the patient's own benefit because regenerative medicine, as opposed to other areas, has the potential to not just help to manage disease but it also has the potential to cure. So that is a very important difference between this field and the potential that it can achieve for our patients in the future.

The second benefit involves health care costs. Basically just imagine that instead of managing diabetes, you could actually cure it. Or imagine that instead of just managing heart disease, you could cure it. So basically it is estimated by very carefully performed studies that the health care costs that could be saved through regenerative medicine is around \$250 billion per year if we were able to achieve a lot of these technologies for just the major disease areas that we deal with.

The third advantage involves economic advantages. It is estimated that the global market by 2013, just 2 years from now, will approach \$118 billion. So there is a major economic benefit that can result through these technologies.

And finally, the fourth benefit is job creation. If we are able to create these technologies here and retain them here in the U.S., we would then be able to establish our manufacturing and commercial facilities right here by preserving the scientific lead in this area, and by allowing these technologies to be produced, we could generate more jobs. And in the biotechnology industry, there is a multiplier effect. For every job that you create in the biotechnology sector, there are approximately 5.7 jobs that are also created.

So to summarize then, our goal is to improve innovation through these technologies, and we are able to improve innovation but we do need several things to happen to make sure that we can do this in the field of regenerative medicine. This includes increased funding to this area.

It includes ensuring intellectual property protection for everything we do and to accelerate the process by which we can do that. That is critical for the commercial strategies that lay ahead for this field. This field is at risk of not accomplishing its goals if we cannot retain the leadership we need worldwide for these areas and these technologies.

And finally, to be able to expand our commercial strategies. And of course, that also depends on our innovative strategies that we can perform.

Thank you, Mr. Chairman and Members of the Committee.

[The prepared statement of Dr. Atala follows:]

House Judiciary Subcommittee
Intellectual Property, Competition and the Internet

Hearing

“Driving American Innovation: Creating Jobs and Boosting Our Economy”

Regenerative Medicine

Strategic Innovation for Patient Health, Economic Benefit, and Job Creation

The U.S. Department of Health and Human Services (HHS), calls regenerative medicine the “next evolution of medical treatments.” Its report, “2020: A New Vision – A Future for Regenerative Medicine,” says the field not only “holds the realistic promise of regenerating damaged tissues and organs in the living body,” but “empowers scientists to grow tissues and organs in the laboratory and safely implant them.” Indeed, regenerative medicine is not a pipe dream, but is already making its mark on health care. Skin and cartilage substitutes are available through regenerative medicine techniques and laboratory-grown bladders, tracheas, blood vessels and other tissues have been implanted in patients.

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Thank you, Chairman Goodlatte, Ranking Member Watt, Vice-Chairman Coble and members of the committee, for inviting me to testify today. It is an honor to be here. Following is my testimony regarding the field of regenerative medicine.

Background

Regenerative Medicine is an interdisciplinary field with scientists in molecular biology, genetics, cell biology, physiology, pharmacology, biomaterials and nanotechnology working collaboratively to deliver therapies that repair, replace or regenerate organs and tissues. The field is composed of the sub-disciplines of tissue engineering, cell therapies, and a new area often called healing therapies.

- Tissue Engineering is the science of growing replacement tissue in the lab to replace damaged or diseased tissue and organs. The process usually starts with a three-dimensional structure called a scaffold that is used to support cells as they grow and develop. Skin, blood vessels, bladders, trachea, esophagus, muscle and other types of tissue have been successfully engineered; and some of these tissues have already been used in treating human disease.
- Cell therapies apply living cells to an organ or tissue to promote healing and regeneration from within. Cell therapies are being delivered today for cartilage reconstruction, bone reconstruction, and in inflammatory and immune response problems. In the future, cell therapies hold promise for treating liver disease, diabetes, neural disorders, renal failure and other chronic conditions. Cell therapies are a promising area of research since it is simpler to heal existing tissues and organs than to replace them.
- Healing therapies are similar to cell therapies in that the goal is to restore the function of a tissue or organ. However, rather than using cells alone, various strategies are currently being studied with promising results, including using biomaterials to aid in cell recruitment for regeneration, and using small molecules to trigger a regenerative effect.

The goal of many regenerative therapies is to use a patient's own cells. These cells can include adult stem cells (found in many organs and tissues, including brain, bone marrow, and the blood) and progenitor cells (an immature type of cell found in almost every organ in the body). In cases where a patient's own stem cells cannot be obtained, there are several sources of stem cells. For example, scientists at the Wake Forest Institute for Regenerative Medicine discovered a type of versatile stem cell in amniotic fluid and placenta (afterbirth). And, using a new technique, stem cells can be created from skin cells.

The Wake Forest Institute for Regenerative Medicine (WFIRM) is recognized as a leader in the translation of scientific discoveries into therapies to benefit patients. Almost 300 scientists and staff collaborate on regenerative medicine initiatives at the institute, which is located in Piedmont Triad Research Park in Winston-Salem North Carolina. Its physicians and scientists were the first in the world to engineer laboratory-grown organs that were successfully implanted into humans. The Wake Forest Institute for Regenerative Medicine is involved in the full spectrum of activities required to move technologies from basic research to commercialization and the clinic. Examples include the following:

- The team is working to engineer replacement tissues and organs and develop healing cell and healing therapies for more than 30 different areas of the body. Several regenerative medicine therapies are already in patients, and others are in the pipeline, ready to begin testing in patients within the next few years. Projects range from treatments designed to cover burn wounds with the patient's own skin cells to the engineering of several tissue structures.
- The institute has seen rapid growth in intellectual property activity since its launch in North Carolina in 2004. The institute has filed a total of 85 invention disclosures and 175 patent applications adding immediate job growth among scientists and offering the

potential for increased job growth as these technologies mature. The number of personnel has increased over 1000%.

- The Wake Forest Institute for Regenerative Medicine facility includes a Good Manufacturing Practices (cGMP) production facility that allows for the preparation of tissues and cell therapies under U.S. Food and Drug Administration guidelines. This facility helps accelerate clinical translation and commercialization.
- The Wake Forest institute is involved as a member of the Armed Forces Institute of Regenerative Medicine (AFIRM), an \$85 million federally funded effort to apply regenerative medicine to battlefield injuries. The partnership involves support from all branches of the military, the Veterans Administration, and the National Institutes of Health. The program is administered through the US Army Medical Research & Materiel Command. AFIRM involves more than 30 institutions across the country working on regenerative medicine therapies. This project has brought significant funding to scientists to rapidly develop new treatments to benefit wounded warriors as well as civilians. Several clinical trials are currently active under this program.

The Potential

Regenerative Medicine, being an innovative new technology, has the opportunity to offer unique health benefits, benefits in effectiveness and cost reduction, and the potential to be the foundation of an exciting new job creating industry.

1. Patient Benefits: Unlike many other technologies, the science of regenerative medicine has the potential to not only manage disease, but also to provide a cure. The health benefit potential to patients receiving regenerative medicine technologies has already been shown with several technologies.

2. Health Care Cost Benefits: Because of its potential to cure – rather than merely treat disease –regenerative medicine offers the opportunity to combat rising health care costs. The opportunity for health care savings in the future is significant. In addition to the obvious benefits of reducing human suffering from disease, regenerative medicine has the potential to positively impact health care costs and workforce productivity and longevity.

Early estimates project that regenerative medicine therapies will result in direct health care cost savings in the United States of \$250 billion per year for the chronic diseases of renal failure, heart failure, stroke, diabetes, burn and spinal cord injuries. These savings are expected to grow as the technologies mature.

For example, according to “Economic Impact of RM, Cell Therapy and Tissue Engineering,” introducing a cure for juvenile diabetes five years earlier – such as in 2030 instead of 2035 – would generated an estimated \$12.5 billion in additional productivity.

3. Economic Benefits: Intellectual property protection in the field of regenerative medicine, as a result of increased funding and innovation, would enable the development and manufacturing of these technologies in the US, rather than abroad. According to Life Science Intelligence, the largely untapped global market potential for tissue engineering and regenerative medicine products will exceed \$118 billion by 2013. When new regenerative therapies are commercialized, there is the potential for new companies, manufacturing centers, medical device companies and added jobs.

Regenerative medicine represents the potential for economic benefit through the growth of companies and research institutions dedicated to its technologies. Some indicators of the economic potential of the regenerative medicine industry include:

- According to a 2001 U.S. National Academy of Sciences report, the potential number of patients who could benefit from regenerative medicine include: cardiovascular disease (58 million); autoimmune disease (30 million); diabetes (16 million).
- As an example, a large health care company entered the regenerative medicine market in 2002 with a bone morphogenic protein used in spine fusion. This became the first blockbuster regenerative medicine product with sales of more than \$600 million four years later.
- In 2008, there were over 500 companies involved in cell therapy.
- According to Global Industry Analysts Inc., "the active support of governments around the world and technological breakthroughs are expected to result in high growth for the industry in the near future."

4. Job Creation: Employment in regenerative medicine is expected to increase as the research infrastructure grows. This will include both the number of working scientists and the potential for new companies based on the technologies they develop. Every new job in this sector could have a multiplier effect of up to 5.7 additional jobs in other employment sectors throughout the community, according to published findings by BIO, the nation's leading biotechnology organization.

- Success in regenerative medicine will assist the United States maintaining its leadership in the health care field. The *US Department of Health and Human Services Report on this field states "...regenerative medicine will be the standard of care for replacing tissue/organ systems in the human body."* Because regenerative medicine has the potential to dramatically alter the health care landscape, it will likely displace traditional therapeutic creating significant opportunities for job producing young companies.

Improving Innovation and Technology Delivery in Regenerative Medicine

There are many things that could be done to increase the pace of innovation and commercialization in the regenerative medicine field. The HHS report recommends a government/academic model for regenerative medicine, citing that a similar model helped grow the nation's semiconductor industry from \$8 billion to \$170 billion in a 10-year period. Funding can help accelerate the translation of scientific discoveries through pre-clinical and clinical trials, manufacturing and commercialization strategies.

Intellectual property protection (patents in the case of most bioscience) helps ensure that new regenerative medicine therapies developed in the United States are commercialized. Since it takes a long time to perform clinical trials and clear the regulatory pathway the current patent process is essential to preserve the competitive position of the invention during this development period. In addition a patent once granted can aid in funding of the technology in a startup or add value to a larger company that licenses the technology for commercialization.

Funding of the technology and the new ventures that use them is essential to the competitiveness of the United States. The risk inherent in new technology ventures makes it very difficult to obtain startup capital for these startups. It is so difficult that this problem has been termed by the entrepreneurial community "the valley of death". A mitigating factor and another area of very important funding are the SBIR (Small Business Innovation Research) and STTR (Small Business Technology Transfer) programs. These programs reserve an allocation of funding to

federal research groups for young companies that are the ones that are actually producing jobs and doing the important work of commercialization to bring technologies to patients. Significantly expanding the allocation of these agencies (such as NIH) so that more money is available for commercialization could be one of the most important things to do to speed innovation.

Streamlining the approval by the FDA of early stage clinical trials is another way that innovation could be improved in regenerative medicine. In recent years, the development of new therapies in the field of regenerative medicine that often involve new science that do not necessarily fit under the currently established regulatory guidelines, has made the regulatory pathway for these technologies difficult. Establishment of new regulatory guidelines that keep pace with the new scientific discoveries in this field, and targeted and collaborative efforts to reduce the cost and streamline the FDA regulatory process, would pay great dividends. This is an imperative for the United States since these regulatory retractions are significantly less in European countries and Asia.

In summary, the support of regenerative medicine, assuring intellectual property protection, expanding commercialization strategies such as SBIR/STTR programs, and streamlining approval of early stage clinical trials will help the United States maintain its leadership position in this sector by accelerating the clinical translation of scientific discoveries, and increase its economic base through manufacturing and job creation.

Appendix: About the Wake Forest Institute for Regenerative Medicine

The Wake Forest Institute for Regenerative Medicine (www.wfirm.org) is an international leader in translating scientific discovery into clinical therapies. Its physicians and scientists were the first in the world to engineer laboratory-grown organs that were successfully implanted into humans. Today, this team is working to engineer replacement tissues and organs and develop healing cell therapies for more than 30 different areas of the body.

Approximately 300 scientists collaborate on regenerative medicine research at the institute, which is part of Wake Forest University and is located in Piedmont Triad Research Park. When complete, the park will be the largest urban research park in the nation. As a premier tenant in the park, the institute is seen as an integral factor in drawing private sector business to the region.

A large number of scientific presentations and publications from the institute's work were highlighted over the last year in media outlets around the world, including 60 Minutes, the CBS Evening News, ABC World News, CNN International, *Smithsonian* magazine, *Newsweek*, and National Geographic.

Achievements of Institute Scientists Include:

- First to demonstrate that complex layered tissue structures can be engineered using cells. (1994)
- First in the world to use biomaterials alone, without the addition of cells, in patients for the regeneration of tissues. (1996)
- First team in the world to create a laboratory-grown organ -- engineered bladder tissue that was successfully implanted in patients. (1998)
- First team in the world to engineer functional blood vessels that were implanted pre-clinically and survived long term. (2001)
- First team in the world to create functional solid organ constructs experimentally, a miniature kidney that secretes urine. (2003)
- Identified and characterized a new class of non-controversial stem cells derived from amniotic fluid and placenta, which show promise for the treatment of many diseases. These amnion stem cells have been proven to differentiate into many tissue types, including blood vessel, bone, liver and muscle. (2007)
- Selected to co-lead the Armed Forces Institute of Regenerative Medicine, an \$85 million, federally funded project to apply the science of regenerative medicine to battlefield injuries. (2008)
- First team in the world to engineer solid organ constructs (miniature human liver tissue and erectile tissue) using a strategy of recycling donor organs, with potential applications to other organs, including the kidney and pancreas. (2010)

Mr. GOODLATTE. Thank you, Dr. Atala.
Dr. Fulkerson, welcome.

**TESTIMONY OF MICHAEL S. FULKERSON, Ph.D.,
CHIEF TECHNOLOGY OFFICER, ROSETTA STONE, INC.**

Mr. FULKERSON. Thank you, Chairman Goodlatte, Ranking Member Watt, and honorable Members of the Subcommittee. I appreciate the opportunity to appear before you today and want to thank you and your colleagues for recognizing the important role that innovation in private industry plays in job creation and the growth of the American economy.

Rosetta Stone epitomizes the critical role that investment in product innovation and development can play in the growth of jobs and business expansion. Innovative product development has enabled Rosetta Stone to grow from a small family-owned business founded in the heart of the Shenandoah Valley in Harrisonburg, Virginia to approximately 2000 employees, most of whom are based in our headquarters in Arlington, Virginia, our main operational facilities in Harrisonburg, Virginia, and a research center in Boulder, Colorado.

Our company was founded on the innovative idea of using computer technology to teach a new language by simulating the way people learn their native language, through the use of visual and audio context, without translation from another language. Our founder's original idea is much older than our company. The advent of CD-ROM and multimedia technologies in the early 1990's gave him a practical means of converting his innovative idea into a viable product. Through continued investment and research and development, Rosetta Stone has utilized technological and pedagogical innovations to create an effective way to learn languages in a convenient and engaging manner. Now available in 34 languages, Rosetta Stone solutions are used by schools, our armed forces, Government agencies, corporations, and millions of individuals in over 150 countries throughout the world. Every day our innovations in language learning help people improve their lives and make the world a better place by improving our ability to communicate.

Rosetta Stone's investments in product innovation and development have dramatically accelerated our growth. Our employee base has grown from less than 300 in 2004 to approximately 2,000 employees today, and our revenues have grown 10-fold from roughly \$25 million in 2004 to approximately \$259 million in 2010. In addition, revenues generated from our international business has grown from a negligible percentage in 2004 to 18 percent of our revenues in 2010. Our company's growth demonstrates the important impact of investment and technology and product innovation on the American economy.

Rosetta Stone's latest major innovation was the introduction of Rosetta Stone Version 4 TOTALE which augments our self-study computer software with live, over-the-Internet conversations with native speakers. We call this future Rosetta Studio. We all recognize that speaking with a native speaker is truly invaluable to learning a new language, and our failure to do so or have the access to do so is one of the reasons many of us have been frustrated with previous language learning attempts.

The problem that faced us in developing Studio is that early learners have a very limited vocabulary, say, 25 words. You would not think you could interact in a language for very long or say anything interesting with so few words. However, the innovations in Rosetta Studio have solved this problem. Our learners get the same sense of accomplishment that our children get early in their development when they first successfully accomplish a goal using language, something as simple as asking for a glass of milk.

It is worth noting since the introduction of TOTALe, our company has hired approximately 250 U.S.-based language coaches to conduct these online conversation sessions with our customers. In doing so, we are exporting the services of these and many other U.S.-based employees to countries around the world as we expand the availability of our product overseas. As TOTALe becomes available in schools, its online features will enable children learning Mandarin to interact online with school children in Shanghai or children learning Spanish to interact with a school in Costa Rica, thereby enhancing not only their language learning experience but also their awareness of other cultures.

In addition to contributing to the growth of our own company, our investments in innovation and development are enabling our customers to take advantage of our products to contribute to their own success. From supporting English as a second language programs in school systems, supporting the U.S. military, preserving endangered languages, to assisting in speech therapy, our customers are finding innovative and often unforeseen ways to benefit from our products.

At Rosetta Stone, we are committed to developing the best commercial language learning solutions through continued investment in innovation to meet our customers' widely diverse needs. At the same time, however, we need to protect our investments from criminals who seek a free ride on the back of Rosetta Stone's innovations and profit from the illicit counterfeiting of our products. Criminals, often operating out of China, Russia, or other foreign countries, routinely offer pirated copies of our products over the Internet. This illicit activity substantially weakens our ability to create jobs and to continue to invest in innovative products. It also tarnishes our brand and harms U.S. consumers. Therefore, Rosetta Stone welcomes any legislative initiatives that the subcommittee may consider to effectively combat the threat posed by online piracy so that criminals cannot continue to harm consumers, innovation, and the growth of the U.S. economy.

Thank you very much.

[The prepared statement of Mr. Fulkerson follows:]

**Testimony of Dr. Michael S. Fulkerson
Chief Technology Officer
Rosetta Stone Inc.
Before the Subcommittee on Intellectual Property, Competition and the Internet
Committee on the Judiciary
Hearing on
“Driving American Innovation: Creating Jobs and Boosting our Economy”
March 9, 2011**

Chairman Goodlatte, Ranking Member Watt, and honorable Members of the Subcommittee. My name is Mike Fulkerson, and I am the Chief Technology Officer of Rosetta Stone Inc., a leading provider of technology-based, interactive solutions for language learning. Our solutions are acclaimed for the power to unlock the language-learning ability in everyone. Available in 34 languages, Rosetta Stone language-learning solutions are used by schools, our armed forces, government agencies, corporations, and millions of individuals in over 150 countries throughout the world. Every day our innovations in language learning help people improve their lives and make the world a better place. These innovations have enabled Rosetta Stone to grow from a family-owned business founded in the heart of the Shenandoah Valley in Harrisonburg, Virginia to approximately 2000 employees, most of whom are based in our headquarters in Arlington, Virginia, our main operational facilities in Harrisonburg, Virginia, and a research center in Boulder, Colorado.

I appreciate the opportunity to appear before you today and want to thank you and your colleagues for recognizing the important role that innovation in private industry plays in job creation and the growth of the American economy. This is particularly true for software companies like Rosetta Stone and for the information technology (IT) industry in general. Continual innovation plays a critical role in these sectors of the economy, with IT companies investing billions of dollars each year in research and development. For example, the Business Software Alliance (BSA), of which Rosetta Stone is a member, has reported that its member companies alone have invested \$26 billion in R&D last year, with some companies investing more than 20% of their revenue. This investment is driving IT employment to new heights. IT employment in the U.S. this year will be approximately 3.1 million jobs, and the BSA estimates that IT employment will grow by 282,000 jobs over the next two years. More broadly, all intellectual property industries employ more than 19 million people and account for

60 percent of our exports, making them the cornerstone of the U.S. economy. These economic gains are in addition to the huge productivity benefits that the software and IT industries bring to our economy. It has been estimated that IT investment was responsible for two-thirds of the productivity gains that this country experienced between 1995 and 2002 and nearly all of the growth in labor productivity. It is difficult to imagine where we as a country would be in terms of global competitiveness without IT investment and innovation.

Rosetta Stone's history exemplifies the critical role that R&D investment and innovation plays in business expansion and job growth. Founded as a family business in 1992, Rosetta Stone had its humble beginnings in a garage in Harrisonburg, Virginia. Its founders had conceived the idea of using computer technology to teach people to learn a new language by simulating the way people learn their native language through the use of pictures and audio in context without direct translation. They developed their initial software product using the then newly developed CD-ROM technology. The company gradually expanded its portfolio of language learning products, and its sales revenues grew to roughly \$25 million by 2004. In 2006, Rosetta Stone was able to attract private equity investments from two investment companies, enabling the company to accelerate its investments in research and product development. As a result of expending well over \$90 million in research and development since 2003, Rosetta Stone has been able to achieve major improvements in the effectiveness and sophistication of our innovative language-learning technologies and solutions. A chart showing the history of our product innovations is attached to this testimony as Exhibit A.

Our solutions provide an effective way to learn languages in a convenient and engaging manner. Our approach, called Dynamic Immersion, eliminates translation and grammar explanation and is designed to leverage the innate, natural language learning ability that children use to learn their native language. We consider traditional translation and grammar methods as obstacles that delay and impede the successful acquisition of language proficiency, and our solutions avoid those elements. Our computer based self-study courses allow our customers to learn using the immersion method on their own schedule and for a price that is significantly lower than most classroom based or one-on-one alternatives. Our proprietary solutions have been developed over the past 18 years by professionals with extensive expertise in linguistic, education and instructional technology. Our content library consists of more than 25,000 individual photographic images and more than 400,000 professionally recorded sound files. We

design the sequencing of our content to optimize learning. The result is a rigorous and complete language learning curriculum that is also designed to be flexible, fun and convenient. Our language learning solutions are built upon a flexible software platform that supports multiple languages and is deployable on personal computers, on local networks and online. The platform incorporates a number of proprietary technologies that are key to enabling language learning, including: (i) speech recognition that is focused on the unique challenges of language learners; (ii) “Adaptive Recall” algorithms that repeat content at scheduled intervals to promote long-term retention; (iii) reporting features and curriculum options designed to enhance the effectiveness and administration of classroom, enterprise and home school learning; and (iv) an intuitive user interface that assists the learner’s transition from listening comprehension to speaking. Rosetta Stone offers a broad product suite, with courses currently available in 34 languages. Our courses are available in up to five levels of proficiency per language, with each level providing approximately 40 hours of instruction and containing multiple units, lessons and activities.

Rosetta Stone’s investments in product innovation and development have dramatically accelerated its growth. Our employee base has grown from less than 300 in 2004 to approximately 2000 employees today, and our revenues have grown by 10-fold, from roughly \$25 million in 2004 to \$258.9 million in 2010. In addition, revenues generated from our international business grew from a negligible percentage in 2004 to 18% of our revenues in 2010. Our company’s growth demonstrates the important impact of investment in technology and product innovation on the American economy.

The company’s technological and pedagogical innovations led to the introduction in 2009 of its latest product offering, Rosetta Stone TOTALe®. With this new product, we have been able to strengthen the effectiveness of our existing language courses with internet-based services that enable our customers to practice conversation in a language with dedicated language coaches in an on-line, interactive environment and to interact with other language learners through online learning games to increase language socialization, and providing live support from customer service agents. Currently, this new product is available to customers in the United States and Japan, and by year-end we will have extended its availability to users in South Korea and several countries in Europe and Latin America. It is worth noting since the introduction of TOTALe, the company has hired approximately 250 U.S.-based language coaches to conduct the online conversation sessions with our customers. In doing so, we are

effectively exporting the services of these and many other U.S.-based employees to other countries as we continue to expand the availability of this product overseas. As TOTALe becomes available in school systems, its online features will enable children learning Mandarin to interact online with school children in Shanghai, or children learning Spanish to interact with a school in Costa Rica, thereby enhancing not only their language learning experience but also their awareness of other cultures. In September, 2010, we released Rosetta Stone Version 4 TOTALe combines our packaged software language learning programs with opportunities to practice with dedicated conversational coaches and other language learners to increase language socialization as well as online language learning games. If the members are interested, I am prepared today to demonstrate for you this latest innovative product offering.

In addition to contributing to the growth of our own company, our investments in product innovation and development have also enabled our corporate, educational, governmental and other customers to take advantage of our products to contribute to their own success. This has created a ripple effect in which Rosetta Stone's innovative products have been adopted by other organizations in innovative and often unforeseen ways, multiplying the benefits derived by society from our own investments. Let me share a few examples with you:

- Supporting English as a Second Language (ESL) Programs in School Systems: With a student population of more than 25,000 in north central Phoenix and East Glendale, Arizona, Washington Elementary School District (WESD) is the largest elementary school district in the state. With an ethnically diverse student population, a large percentage of whom do not have a basic knowledge of the English language, WESD faced the challenge of integrating its large population of non-English speaking students into the district's education system and providing the best education to all of its students. With a limited budget and staff, WESD decided in 2005 that Rosetta Stone's Classroom Edition product would best fit its needs in implementing a new ESL program. WESD installed Rosetta Stone Classroom software onto all of its language lab computers. One year later, the language-learning solution was available on every computer throughout the school district. "We needed a single solution that allowed a wide range of students from different grades, backgrounds and proficiency skills to attain language skills at their own individual pace," said Sue Brown, administrator for ESL Programs in WESD. "Rosetta Stone Classroom helped us create effective multi-age programs where ESL kids could naturally learn English in an immersive and personalized environment."
- Supporting the U.S. Military: First adopted by the U.S. Army in 2005, Rosetta Stone programs have successfully delivered more than 1.3 million hours of language training to the military's globally deployed forces. Last year, we released six new language editions, available for military and government language-training platforms, in Dari, Pashto, Urdu, Arabic (Iraq), Swahili and Bahasa Indonesia -- languages critical to global security

efforts. Blending the Rosetta Stone curriculum with custom military terms and content in these mission-critical languages, these newest product offerings are helping to build foundational language skills through immersion-based, self-paced study and simulated exercises that prepare for real-life, face-to-face interactions. The new mission supporting content includes modes of transportation, weapons and ammunition, directions, buildings and landmarks, natural features, basic medical terms and relevant cultural concepts. The learner plays the part of a security force member who must effectively engage in conversations in order to accomplish missions. Forces deploying to regions where these new languages are spoken will have the opportunity to access these new language editions to prepare them to communicate more effectively in everyday interactions.

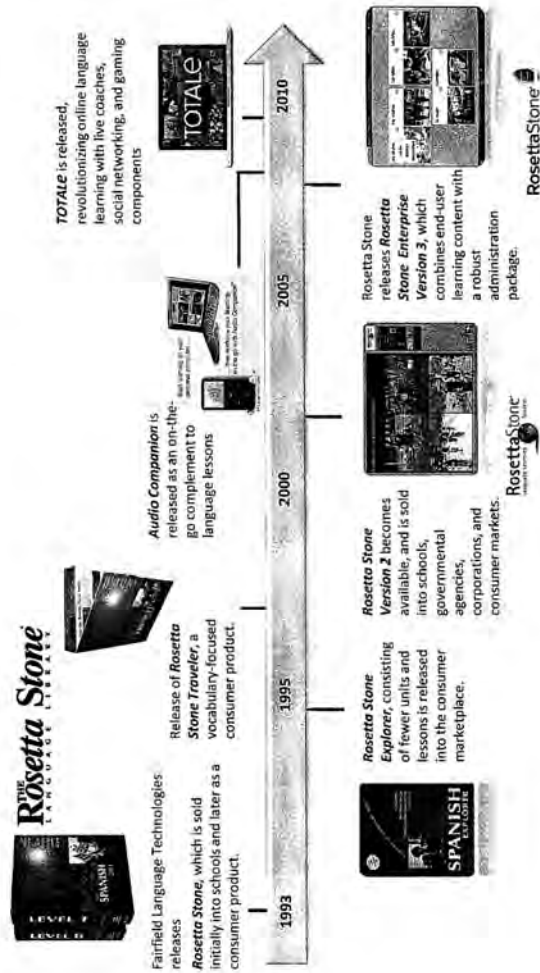
- Preserving Endangered Languages: In 2004, Rosetta Stone launched its Endangered Language Program, an effort devoted to collaborating with indigenous groups in the U.S. and elsewhere to develop Rosetta Stone software specifically designed to help teach, revitalize and restore at-risk or “dying” languages. Through this program we have worked with the Chitimacha Tribe of Louisiana to create Rosetta Stone Chitimacha software that is now in use in tribal schools. This is making it possible for the children of the tribe to learn their heritage language, even though the last fluent speakers of the language died in the early 20th century. This leap from a language that previously existed only in archival form to one which can now be learned using state of the art technology is an unprecedented example of the application of technical innovation. Rosetta Stone has now developed software for seven different endangered languages across the United States and Canada, and these programs are being used in schools in Alaska, New Mexico, Arizona, Utah, Louisiana, Quebec, and Labrador by hundreds of Native American students. The Rosetta Stone Endangered Language Program has captured the attention of other indigenous communities worldwide, who also hope to incorporate innovative technology into their language revitalization programs.
- Assisting in Speech Therapy: There is growing evidence that our language learning software may offer exciting opportunities for use as a tool in speech therapy for individuals with certain cognitive and physical disabilities, such as autism, cerebral palsy, autism, and aphasia. Technical components and methodology, pacing, and other aspects of Rosetta Stone programs may enable our software to be conducive to instruction and therapeutic efforts. I have attached an article entitled “Inclusion Tools: Rosetta Stone – A Visual Way to Teach Language” by Pam Corley and Merry Fore as Exhibit B to my testimony which discusses the potential for using Rosetta Stone software as a therapeutic tool.

At Rosetta Stone, we are committed to developing the best commercial language learning solutions through continued investment and innovation to meet our customers’ widely diverse needs. At the same time, however, Rosetta Stone needs to protect this investment from those who seek to profit from the illicit counterfeiting of our products. Rosetta Stone’s heavy investment in developing and launching new products would be put at risk if counterfeiters could reap the benefit of Rosetta Stone’s efforts by selling pirated copies of the products as soon as we

launch them. Yet, this kind of theft of our intellectual property routinely occurs through online piracy, and it is having a negative impact on our ability to maintain and create jobs and to attract the capital needed to invest in new products and services. In effect, criminals seeking to profit from our investment in new products by selling pirated copies of our products over the Internet weaken our ability to grow and continue to invest in innovative product improvements. They also tarnish our brand and harm consumers by selling poor quality or defective copies of our software. Most of these pirates are based in China, Russia and other foreign countries, beyond the reach of U.S. law enforcement. Therefore, Rosetta Stone welcomes any legislative initiatives that the Subcommittee may consider to combat effectively the threat posed by online piracy to the benefits that otherwise would be derived from innovation by American companies.

ATTACHMENT

History of Innovations



Inclusion Tools: Rosetta Stone

A Visual Way to Teach Language

By Pam Corley and Merry Fore

In too many classrooms, there is no expectation that learners with special needs will be able to learn and develop functional reading and writing skills. This is especially true for children with complex communication needs (CCN). Teachers in public schools, trying to teach children with disabilities, who require assistive technologies, to read and write in an inclusive setting may find the task overwhelming.

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One of the biggest problems for teachers and therapists working with these students is the lack of ready-made instructional and assessment materials that can be used by learners with a range of physical and cognitive disabilities. Let's face it, adapting materials so that learners with CCN can be actively involved is a tremendous amount of work. Even with the best intentions, there is just not enough

time in the day for teachers to keep up with the general education curriculum and adapt the materials for students with more significant disabilities, like those who cannot use pen and paper or who cannot speak.

While teachers of general education students have pre-made activities (such as exercises, worksheets or other assessment materials) that can easily be downloaded or photocopied for their students to use, teachers of children with disabilities often have to make their own, which is prohibitively time-consuming. Teachers of general education students can find out how learners are progressing by asking questions and receiving oral responses. Teachers of children with CCN cannot rely on oral responses, since a great number of these students cannot speak. In many cases, teachers of individuals with significant disabilities don't even follow a specific reading or writing curriculum. This scenario provides inconsistent outcomes for learners who are most at risk for learning failure.

So, do we just give up on teaching literacy skills for these learners? Of course not! We have to get creative and figure out how we can use ready-made programs and resources in innovative new ways.

This is the first in a two-part series, written to share ideas that work in the inclusive classroom and spark your creativity to think differently about resources you may already have available or can easily acquire. This article will focus on the use of the language learning software Rosetta Stone, not to learn a foreign language, but to teach

and assess language in students with CCN.

These learners often have gaps in their language and literacy development, but it is very difficult to find the gaps or "splinter skills." Many times teachers end up teaching the same things over and over again because they don't know when to move on to the next level due to lack of proper assessment materials. A ready-made systematic language instruction program can help us find the gaps and provide a way for learners who cannot be assessed in traditional ways to demonstrate their literacy skills.

We are not affiliated in any way with Rosetta Stone; we just ordered a demo, wondering if, perhaps, the program could be used in a different way than the designers originally intended, desperate for a tool that we didn't have to design and create ourselves. Once we started using the demo and then the full program, we realized its potential. The more we have used it, the more impressed we have been. Here are some unique features that we feel make Rosetta Stone a great fit as a language-teaching tool for learners with disabilities, such as autism and cerebral palsy.

FIRST, IT IS ENGAGING, ALWAYS A PLUS!

It is an interactive, multimedia computer program that incorporates words, sounds and imagery. Instead of the clip-art we see so often in programs designed for students with disabilities, Rosetta Stone matches spoken words and text with photographic images from real life. The program teaches language by the association of words and meaning derived from images. It presents a series

of vivid photos, and a word or sentence describing the photo is spoken while the text is displayed on the screen. The learner then selects which picture goes with that word or sentence. The learner advances using language they've learned and clues from new images. Learners constantly interact with the program to confirm their intuition and check what they have learned. If they're right, they proceed. If not, they get another chance. It starts simply and builds systematically to the more complex.

The clear, colorful photographs are engaging for all kids, but can be especially appropriate for kids on the autism spectrum who are often visual learners. Dr. Yempe Grandin, a prominent author and speaker with autism, wrote: "I think in pictures. Words are like a second language to me. I translate both spoken and written words into full-color movies, complete with sound, which run like a VCR tape in my head. When somebody speaks to me, his words are instantly translated into pictures."

SECOND, IT IS ACCESSIBLE, ANOTHER BIG ISSUE FOR THIS POPULATION

It is ideal for students who do not have the motor skills to do traditional worksheets and grammatical exercises with pen and paper. Also, the layout of the program lends itself for use by learners who do not have the motor skills to use a computer mouse and need a touch screen.

CORE COMPONENTS OF THE PROGRAM

LISTENING This is a critical skill, but especially difficult for non-speaking students (e.g. the difference between the sounds "king" and "ning" as in "cooking" and "running"). Some of the activity screens in Rosetta Stone are designed to

specifically focus on listening skills. They do not have text. The words are spoken and the learner chooses the picture that best matches the phrase heard.

WRITING The writing portion can be accomplished by typing a word or sentence using a traditional keyboard or by using the mouse to click the on-screen keyboard. Writing words this way is much easier for learners who struggle with handwriting since they can concentrate on the function of the letters and words and don't have the extra work of trying to write the letters. Users who do not have the motor skills to use a traditional keyboard or a mouse can use their AAC device as input instead. Many dynamic screen devices (such as those manufactured by DynaVox Technologies and Prentke Romich Company) can be connected for either cabled or wireless access via the USB port. Using the device for writing gives AAC device users great practice learning the vocabulary in their devices, as well.

READING The vivid photos and realistic situation portrayals make reading more interesting. Visual supports can be helpful for students learning to read and write, especially students on the autism spectrum. Some screens in Rosetta Stone are designed to reinforce reading skills. The written word or phrase appears, but is not spoken, and the learner must discern which photo best matches the phrase. Some screens use text as a prompt at the top of the screen to be matched with pictures or text boxes below. For example, one screen might have a prompt, "The dog is swimming." There are four pictures, one of a dog swimming in the water, a close-up of the face of a dog, a close-up photo of a horse and one of a horse running. Just knowing the word "dog" isn't enough because there are two pictures of dogs,



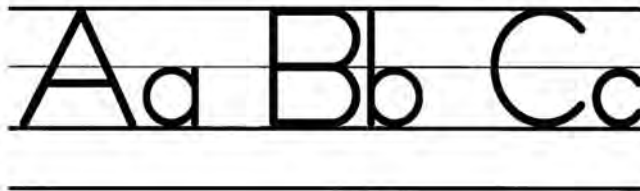
"Reading Practice in Rosetta Stone Level 1"



"Grammar Practice in Rosetta Stone Level 1"

so the user must also know the word "swimming" to respond correctly.

SPEAKING Wait a minute, isn't that the problem with students with CCN? Why do we say "speaking"? Because this program's sophisticated speech recognition makes it possible for both speaking and non-speaking students to practice "speaking." How does that work, you may wonder? Well, when doing the microphone setup, the user is asked to say ("1, 2, 3, 4, 5") in a normal speaking voice so that the program can recognize the voice. For students who use an augmentative communication device, put the



microphone headset near the speaker on the device and have the device "speak" the numbers. You even have the option to specify whether it is a male or female adult voice or a child's voice and to specify the speech precision level (i.e. difficult, normal or easy). Sometimes you have to play around with these settings to achieve the optimum level for AAC device users. Once the microphone setup has been done, the AAC device user would then use the device to produce words and phrases in the Speech Practice portion of the program. To make the "speech" of the AAC device easier for the program to distinguish, we have a couple of suggestions. 1) a high-quality microphone is needed, like the USB microphone headset that is included when you purchase the Rosetta Stone program. 2) minimize background noise.

VOCABULARY: Many times teachers only use single meaning symbols to teach simple language concepts to special needs students. In Rosetta Stone, vocabulary words are visually presented in authentic contexts and real life situations. For example, in teaching the word "ladder," a photo of men in work clothes carrying a ladder appears and the sentence "The men have a ladder" is presented. Then, a photo is shown of a man reaching for light fixtures on the ceiling to change the bulbs, but clearly cannot reach them. This sentence is presented as a prompt: "The man needs a ladder." Also most helpful for students with autism is the fact that when a photo is presented to teach a specific word, several different photos of the same item are shown. For example, when teaching the word "boy," photos of many different boys are presented, and when teaching the word "egg," the program shows a photo of a raw egg in the shell, as well as cooked eggs on a plate.

GRAMMAR: Rosetta Stone teaches grammar concepts, such as subject-verb agreement in naturally-occurring contexts. For example, a photo of a girl with dirty hands in front of a sink is shown with the prompt "She _____ soap." The choices presented are need/needs. Or a photo of a couple in a market buying vegetables is shown with the prompt "_____ buying vegetables." The choices presented are they/they're.

PRONUNCIATION: This feature of the program helps kids with natural

speech "breakdown" words. We have not found a way for this to work for AAC device users.

How do these core components fit in with literacy research? "Reading, writing, speaking and listening abilities develop concurrently and interrelatedly, rather than sequentially" (Koppenhaver et al, 1991; Teale & Sulzby, 1986).

PROVIDES CORE VOCABULARY PRACTICE FOR AAC DEVICE USERS

As a side benefit, Rosetta Stone is also a great tool to help students who use AAC devices learn and practice the use of core vocabulary. The term "core vocabulary" refers to those top 100 words that account for about 50 percent of the words we use every day. We have found that the language taught by Rosetta Stone almost perfectly coincides with core vocabulary, and that was an exciting extra discovery. AAC device users need lots of practice using these core words and learning the motor plan for accessing them on their device if they are to be effective communicators. Since Rosetta Stone was designed as a language-learning software, and anyone trying to master a foreign language must use the new words they are learning over and over again, it provides that practice.

"What a fabulous idea to use Rosetta Stone software to help students with severe communication disabilities enhance their language and literacy skills. Rosetta Stone can easily be incorporated into curriculum by educators and SLPs." Nancy L. Inman, M.A.T., CCC-SLP

The school version of the program offers teacher and administrative tools to view students' progression through lessons, note potential areas of additional focus, and access easy-to-read reports and graphs. A curriculum editor lets teachers customize courses for individual or classroom development needs. Rosetta Stone Homeschool offers several course options and a full-year lesson plan, complete with lessons, worksheets, quizzes, tests and answer keys, and is easy for parents to use. A mother who is using Rosetta Stone to help her non-verbal son with autism and auditory processing deficits learn language concepts reports the following about her experience:

"Using Rosetta Stone, I have been able to quickly determine my son's areas

of weakness and provide him with direct instruction and activities in those areas. I can print out the words targeted in each lesson and pre-teach them in preparation for a lesson, or use them to generalize. He is successfully advancing and increasing his auditory comprehension skills, word recognition skills and reading skills. For example, at first he had difficulty discriminating between the words "woman" and "women," but the lessons and practice in Rosetta Stone helped him to master those words. Also, I appreciate the value of the realistic photos in Rosetta Stone. I have realized that, although my son could match a written word to a picture symbol on a worksheet, he was not generalizing this knowledge to his real life experiences. Completing the Rosetta Stone lessons that are rich with actual photo representations of language and concepts has helped my son to improve his understanding of words in his daily life."

This is just one example of how we can utilize resources and programs in novel ways to give students with disabilities the extra help they sometimes need to be successful. Our next article in this series will discuss ideas for combining readily-available resources and programs to quickly and easily create literacy lessons for your students.

AUTHOR INFORMATION

Pam Corley is a technical trainer/facilitator who is also the parent of a child with complex communication needs. She can be contacted by e-mail at <pcorley@stbur.com> or by phone at 361-288-5733.

Merry Fore is a teacher with 18 years of special education teaching experience who maximizes the use of assistive technology in her teaching strategies to ensure access to the general education curriculum for all students. She is a former teacher of students with significant disabilities, including many who used augmentative and alternative communication. She can be contacted by e-mail at <merrycuatro@yahoo.com>.

Mr. GOODLATTE. Thank you, Dr. Fulkerson.
And Dr. Smith, we are pleased to have your testimony.

TESTIMONY OF SCOTT SMITH, Ph.D., PROFESSOR AND CHAIR, DEPARTMENT OF MECHANICAL ENGINEERING AND ENGINEERING SCIENCE, UNIVERSITY OF NORTH CAROLINA AT CHARLOTTE

Mr. SMITH. Chairman Goodlatte, Ranking Member Watt, full Committee Ranking Member Conyers, Vice Chair Coble, it is a great honor for me to testify before you today.

Innovation is the foundation of our modern society and the continuing source of strength in our economy. To ensure continued prosperity in the United States, we must continue to innovate and such innovation requires that we have laws, regulations, and policies that foster innovation.

During my introduction, you heard that I am chair of mechanical engineering at the University of North Carolina at Charlotte. UNC Charlotte is a relatively new university founded after World War II. Our annual research budget is small compared to many other universities, on the order of \$35 million annually. We have particular expertise in optics, bioinformatics, and precision metrology and manufacturing which is my area.

While we are young, we have some impressive distinctions. UNC Charlotte has consistently ranked in the top five of all universities for number of inventions created, number of patents issued, number of new companies created per research dollar spent. Over the past 10 years at UNC Charlotte, we have created 541 new inventions, received 67 issued patents, and formed 38 new start-up companies. Innovation is important in North Carolina generally and at UNC Charlotte especially.

Our department houses one of the best dimensional metrology laboratories in the world and one of the highest concentrations of faculty researchers in manufacturing.

The prestigious International Academy for Production Engineering allows no more than 20 fellows per country. Of the 16 current U.S. fellows, four are in our department. All of them have strong industry research partners. Faculty and students in our department have founded more than 10 start-up companies in recent years.

I was personally instrumental in the development of technologies used to stop vibrations in machine tools and to replace sheet metal assemblies by monolithic machining. These technologies have saved billions of dollars in the aerospace industry. I am an inventor on 15 UNC Charlotte patent applications, one of which was recognized as one of R&D Magazine's top 100 inventions of 2010. I am working with industry to help bring this invention to the marketplace.

UNC Charlotte has a history of working closely with industry and commercializing innovation. On average, about 20 percent of our research funding comes through industry. By comparison, the average amount of industrially sponsored research for American universities is only about 5 percent.

University research can take innovation only so far. Innovations often need substantial additional investment and development for successful commercialization, and patents do three principal things that promote commercialization. They decrease risk by ensuring that if research leads to innovation, the effort can be protected. Because the risk is reduced, patents induce investments. Patents allow for an innovation to be quantified. Intellectual property is often the only tangible asset that a new company has.

Collaboration between universities and industry is certainly important for our country. Even in a supportive environment, few patents become products. By some estimates, less than 2 percent of all patents that are issued are ever embodied in a commercial product.

Nevertheless, patents are a necessary tool for turning many types of ideas into products. What company would fund research work at a university like mine if the results could not be protected by a patent? Who would make the investment required to turn an innovation into a product if others could easily copy that product after the expensive work was done?

While virtually every industrialized country has its own patent office, the U.S. Patent and Trademark Office was one of the first and is one of the most developed. Both foreign and domestic inventors apply for patents in the U.S. Many of the inventions are patented only in the U.S. because the U.S. market alone is often large enough to justify the costs of commercialization.

To maintain and grow the U.S. economy, we need a strong patent system that encourages investment and innovation and rewards inventors and risk-takers. Specifically, inventors, particularly university inventors, need the 12-month grace period to file the patent after a publication or presentation. Universities, small businesses, and independent inventors benefit from "first to invent" over "first to file." A three-tier fee system could make it more affordable for small companies and independent inventors to obtain patents.

Better quality patent reviews could be achieved by allowing third parties to submit printed references to the patent office for a pending patent, and by allowing the patent office to retain more of its fees for their own operations.

This concludes my oral testimony, Mr. Chairman. I am happy to answer any questions you may have. Thank you.

[The prepared statement of Mr. Smith follows:]

SMITH written statement

Chairman Goodlatte, Ranking Member Watt, members of the subcommittee, it is a great honor for me to testify before such a distinguished body on the important issues surrounding intellectual property and competition.

Importance of Innovation

Innovation is the foundation of our modern society, and the continuing source of strength in our economy. To insure continued prosperity in the United States, we must continue to innovate, and such innovation requires that we have laws, regulations, and policies that foster innovation.

Background on UNC Charlotte

I am Chair of Mechanical Engineering at the University of North Carolina at Charlotte. UNC Charlotte is a relatively new university, founded after World War II. Our annual research budget is small compared to many other universities, on the order of \$35 million annually. We have particular expertise optics, bioinformatics, and precision metrology and manufacturing (which is my area).

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Faculty in our department invented the software correction used to improve the accuracy of virtually all coordinate measuring machines (CMM's) used throughout the world. We worked on the design and manufacture of the new encasements for the US Constitution and Declaration of Independence. We worked on the design and manufacture of parts for the national ignition facility. We are home to research centers in Precision Metrology, Biomedical Engineered Systems, Energy Production and Infrastructure, and Motorsports and Automotive Research. Our department houses one of the best dimensional metrology laboratories in the world, and one of the highest concentrations of faculty researchers in manufacturing.

The prestigious International Academy for Production Engineering (CIRP) allows no more than 20 Fellows per country. Of the 16 current US Fellows, 4 are in our department: Dr. Matt Davies, Dr. Chris Evans, Dr. Bob Hocken, and me. All of these researchers have strong industry partners. Faculty and students in our department have founded more than 10 start-up companies in recent years.

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Patents are important for Commercialization

University research can take innovation only so far. Innovations often need substantial additional development and investment for successful commercialization. Patents do three principal things that promote commercialization

1. They decrease risk by ensuring that if research leads to innovation, the effort can be protected. Management and minimization of risk is perhaps the most important consideration when developing a new product. There will always be risk that a new technology cannot be produced in a commercially viable manner or that it may fail to create a market or gain market share. If, on top of these risks, a company does not have a way to prevent its competitors from copying the new product then the company's incentive to produce the new product decreases dramatically.
2. Because the risk is reduced, patents induce investments. Before investing in a new company, investors spend significant time and money evaluating the strength of the company's intellectual property. Without patents and their presumption of validity, the venture capitalists' risks would be much higher and so their incentive to invest would be much lower. Patents are like a valve that allows capital to flow, and without them the flow would dry up. Similar considerations apply when an existing company chooses to create a new product – development costs for a prospective new product that is protected by a patent is much more likely to be funded than are development costs for an unprotectable idea.
3. Patents allow innovation to be quantified, clarified, and packaged. In a very real sense, a patent is a way to package an idea. The claims of a patent spell out exactly what the patent protects. This clarity makes it easier for people to understand what they are investing in and gives them something tangible to evaluate when deciding whether to develop a new product or invest in a company. Intellectual property is often the only tangible asset a new company has.

Academic – Industry Partnership

Collaboration between universities and industry is certainly important for the country. Recent decades have seen companies focus more and more closely on developing specific products rather than expanding the frontiers of knowledge, and companies that once had large research divisions have largely shrunk or even eliminated those divisions. It has fallen to research institutions such as universities to take up the important work of performing research and to come up with the fundamental new studies that will lead to the products of the future. Drug discovery, advanced manufacturing, nanotechnology, microelectromechanical devices, photonics, and many of our advanced medical technologies are all largely the result of research from academic institutions and federally funded laboratories. The patents that these institutions generate give us the ability to "package" our ideas, find or create industries capable of using

them, and ultimately transfer our discoveries out of the laboratory and into everyday use, creating jobs and improving our standard of living.

When industry sponsors research at universities it often wishes to own the patentable results of that research. For various reasons (including maintaining the tax exempt status of the universities) this is often not possible, but universities are able to license the patentable results of this research to the sponsors. Industry clearly would like to know how much such a license would cost before committing to support the research, but in many cases IRS Revenue Procedure 2007-47 (found at <http://www.irs.gov/pub/irs-drop/rp-07-47.pdf>) prohibits the university from being able to set this cost in advance – and it also requires the university to charge the sponsor of the research the same amount for the license as it would charge to any other party, even though the other party did not underwrite the costs of the research that led to the invention. It is clearly a disincentive for American businesses to work with universities because those businesses cannot know how much it will cost them to use the results of the research that they pay for until that research is completed.

The difficulty stems from the fact that many universities build and renovate their research facilities using tax-exempt bonds. The revenue procedure says that in most cases if any research work is conducted in those facilities using funds provided by a sponsor other than the US government, the university cannot set any economic terms for a license to the expected results of that research until an invention has actually been made and that the university cannot charge the sponsor a lower cost than it would charge any other party. The revenue procedure does include “safe harbor” provisions that allow a small percentage of research to be carried out in such facilities without being subject to these restrictions, but the wording of the safe harbor provisions is so opaque that one cannot determine if it applies to a percentage of square footage of the facilities, to a percentage of the cost of building the facilities, or to some other percentage basis. In the face of this ambiguity most universities feel that they must interpret the rules very conservatively. This is, unfortunately, the prudent course of action because the results of violating the revenue procedure could include the loss of the bonds’ tax exempt status. Because the aggregate value of these bonds is frequently in the range of hundreds of millions of dollars, the consequence of violating the revenue procedure could be truly ruinous to the universities. This revenue procedure should be repealed, or at least the “safe harbor” language should be clarified so that universities are not left in a position in which they are incentivized to accept the most conservative interpretations of the revenue procedure.

Support for Innovation

The US patent system has not had a major reform in nearly sixty years, so it is appropriate for Congress to revisit it now and make needed changes. By making only relatively small changes to the patent system Congress is missing an opportunity to support American innovation more effectively.

Even in a supportive environment, few patents become products. By some estimates, less than two percent of all patents that are issued are ever embodied in commercial products. Nevertheless, patents are a necessary tool for turning many types of ideas into products. What company would fund research work at a university like mine, if the results could not be protected by a patent? Who would make the investment required to turn an innovation into a product if others could easily copy that product after the expensive work was done?

While virtually every industrialized country has its own patent office, the US Patent and Trademark Office was one of the first and is one of the most developed. Both foreign and domestic inventors apply for patents in the US. Many of the inventions are patented only in the US because the US market alone is often large enough to justify the costs of commercialization. To maintain and grow America's economy, we need a strong patent system that encourages investment and innovation, and rewards inventors and risk takers.

Inventors, particularly university inventors, need to maintain the 12 month grace period to file their patent after a publication or presentation. The very nature of university research, with its imperative to publish causes many inventors to publish their ideas before the full patentability and commercial value has been determined.

Universities, small businesses, and independent inventors benefit from "first to invent" over "first to file". Going from a "first to invent" system to a "first to file" system seems likely to hurt individual inventors and small companies and may face some serious constitutional challenges. Small inventors do not have the resources to engage in a race to the patent office for every potentially patentable idea. Indeed, "first to file" might simultaneously result in a large number of poorly prepared patent applications (increasing the backlog), and a financial barrier further excluding small and very small inventors. While "first to file" provides some measure of clarity, it does not support innovation broadly. A 3-tier fee system, replacing the current 2-tier system could make it more affordable for small companies and independent inventors to obtain patents.

Better quality patent reviews could be achieved by allowing third parties to submit printed references to the patent office for a pending patent, and by allowing the patent office to retain more of its fees for their own operations. Because the backlog at the patent office is so high, many patent applications are not even examined for several years. Many initial reviews amount to keyword searches of existing patents. Allowing third parties to submit printed references essentially allows interested parties to assist the patent office in identifying relevant prior art.

This concludes my testimony, Mr. Chairman. I would be happy to answer any questions you, Ranking Member Watt, or other members of the subcommittee have. I thank you.

ATTACHMENT

Department of Mechanical Engineering and Engineering Science



Department Facts

- Over 800 undergraduates
- Approximately 25th by size
- Nearly 100 graduate students
- 4 Research Centers
 - Center for Precision Metrology
 - Center for Biomedical Engineering Systems
 - Energy Production and Infrastructure Center
 - North Carolina Motorsports and Automotive Research Center



Faculty

- 39 Faculty
- 5 Concentrations
 - Precision Manufacturing
 - Biomedical Engineering
 - Motorsports
 - Computational Modeling
 - Energy

Facilities

- Duke Centennial Hall
- Woodward Hall
- Cameron Center



UNC CHARLOTTE
The WILLIAM STATES LEE COLLEGE of ENGINEERING

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The Department of Mechanical Engineering at
UNC Charlotte
is home to one of the world's best
Dimensional Metrology Laboratories
(Metrology is the science of measurement)

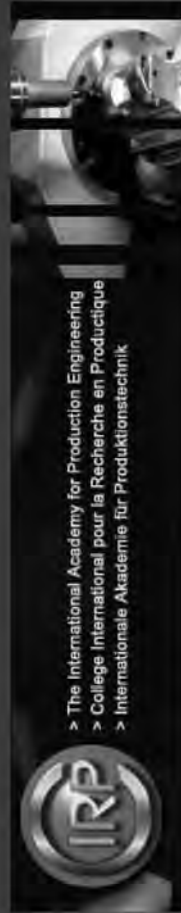


0.3mm step

X (mm)

Time (sec)

UNC CHARLOTTE
The WILLIAM STATES LEE COLLEGE of ENGINEERING



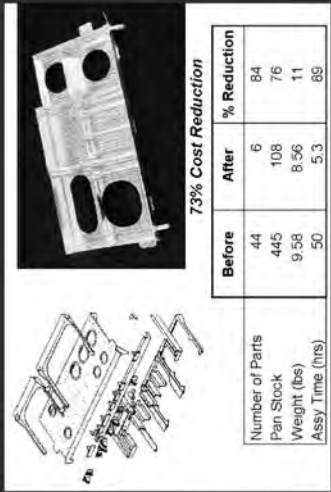
UNC Charlotte has the Highest concentration of CIRP Members in the world
(16 US Fellows, no more than 20 / country allowed, 170 worldwide)

Evans - Fellow

Davies - Vice Chair of the Cutting Group, Fellow

Hocken - Past President, Fellow

Smith - Chair of the Machines Group, Fellow



UNCC was instrumental in creating the technology to manufacture components with thin walls and thin floors.

Raw stock
2,449 kg

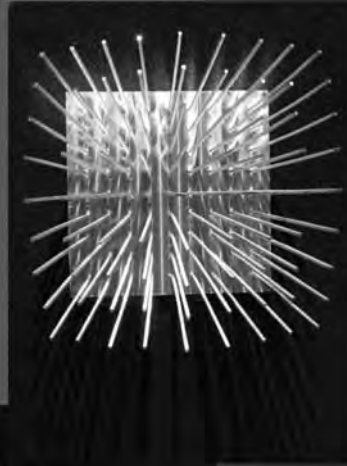
Completed part
113 kg

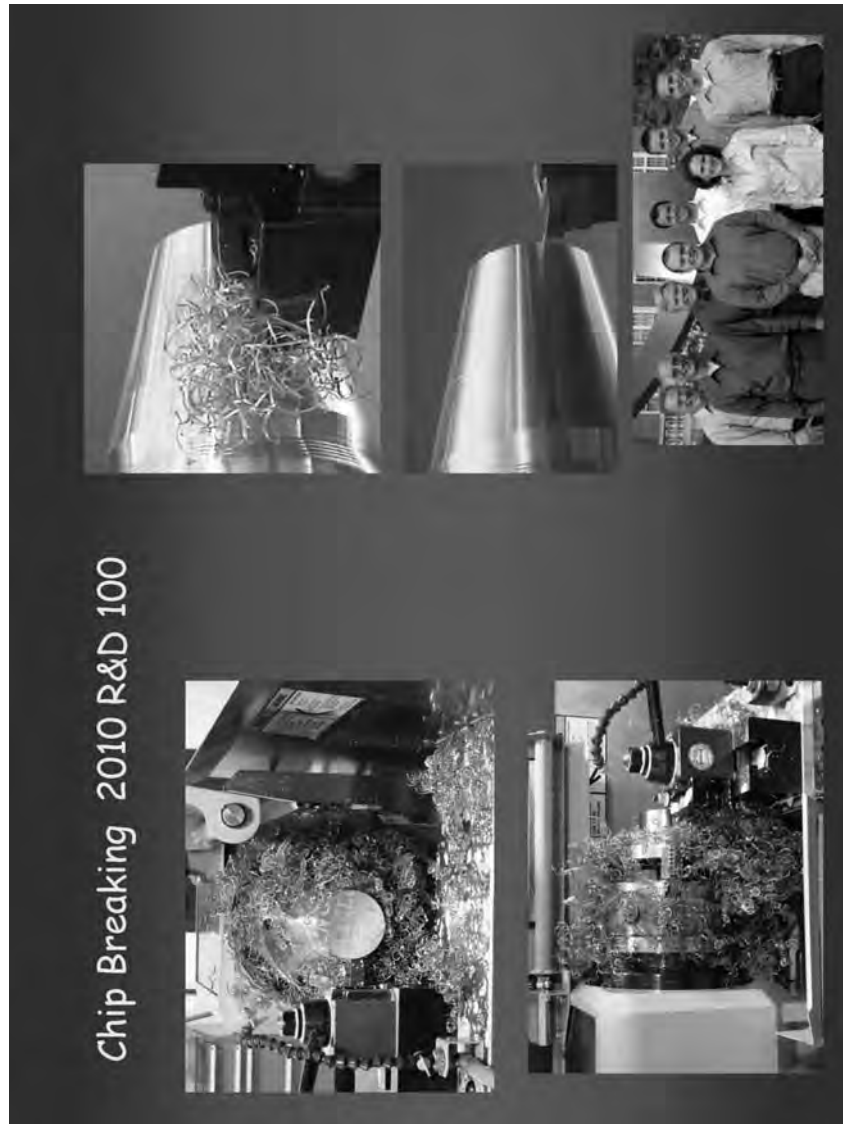
3 m x 1.7 m x 14 cm
9.8' x 5.6' x 5.5"



Part of the raised cargo floor for the flight deck of the Boeing 777-300ER

Thin Part Geometries





Chip Breaking 2010 R&D 100

Mr. GOODLATTE. Thank you, Dr. Smith.

Before we go to our usual round of questioning, each of our witnesses has a presentation. So we will start with you, Dr. Atala. I understand you brought some visuals and items from the lab of actual organs and tissues that you have created and I would like you to share with us how far regenerative medicine has come and what the future may hold.

Dr. ATALA. Thank you, Mr. Chairman.

[Video shown.]

Dr. ATALA. I want to just give you a few examples of regenerative medicine and just to remind everybody why we are doing this. The fact is that every 30 seconds, a patient dies from diseases that could be treated with tissue replacement. That is why we are relying on your own ability to regenerate, the patient's own ability to regenerate.

So what you see here on the left is actually an injured organ, and what you see in the center is actually a smart biomaterial that we developed. And we then use this biomaterial alone to actually replace your tissue. So we replace the top portion of that injured area that you see here, and by replacing that top portion with a scaffold, the cells are actually able to walk on that smart biomaterial and fully regenerate. And when you take a tissue biopsy from this patient, you actually can see the full organ regenerated just using these smart biomaterials. And that actually has been used now in patients. This was the first demonstration of this technology back in 1996 in patients, and that is now being done.

The strategy here for all of regenerative medicine is that for larger defects, you absolutely need the patient's own cells because you can only use smart biomaterials for short distances. For larger distances, you do need the patient's own cells. So the concept is you take a small biopsy from the diseased tissue or organ, less than one-half the size of a postage stamp. We then are able to take those cells, expand them outside the body, create these three dimensional biomaterials, and then place the cells on those biomaterials to replace the tissue.

You are seeing a bioreactor with muscle, engineered muscle. The same concept here. We take the biomaterial. We take a very small piece of the patient's muscle. We grow the cells outside, place those cells on these scaffolds, and then we start stretching that engineered muscle so we can exercise it before implanting them.

Here is another strategy that we use to create blood vessels. This is actually an engineered blood vessel. What you see here is a scaffold that was tubularized. We place the patient's muscle cells on the outside of that tube, the blood vessel lining cells on the inside, and to the right you see a carotid artery that was replaced using these techniques experimentally. That is the vessel that goes from the neck to the brain.

This is actually a bladder, a more complex organ. This is actually showing you the engineered organ in a patient, and this is actually showing you the scaffold and how we seed those in patients.

This actually is another hollow organ which is a little bit more complex. This is an engineered heart valve that we are creating. You can see here the heart valve itself that has been now coated with the cells, and we are exercising the heart valve so it knows what to do. You can see here the leaflets opening and closing from the structure so that we can implant these. This is still also experimental.

This is actually work that we are doing with the Armed Forces Institute for Regenerative Medicine where we are creating engineered ears, and this is actually showing you how we seed those and place them in this oven-like device that actually has the conditions of the human body.

Another project also for the DOD is engineering these digits. You can see here we are actually placing the bone cells in the central portions. We would place the cartilage and then we would use those muscle strips I showed you in that first slide to actually finish off the digit. This is still, of course, experimental.

Solid organs are by far the most complex, and this shows you a strategy that we used early on. This is actually a desktop inkjet printer. We just showed you the inkjet cartridge, but instead of using ink in the cartridge, we use cells. You can see the desktop inkjet printer going back and forth actually printing this two-chamber heart. It takes about 40 minutes to print a two-chamber heart. About 4 to 6 hours later, you can actually start to see the little heart beating. You can see the heart structure is beating away, and this is, of course, also experimental for solid organs which are more complex.

Another strategy for solid organs includes more sophisticated printers where we actually use x-rays. We are able to go down three-dimensionally in these x-rays and we are able to get right down to the organ. And by looking at the organ itself—in this case, it is a kidney—we are able to three-dimensionally rotate the image of this patient's x-ray and take the information necessary to actually create the CAD printing that goes on. We take this information down for the CAD printing into the computer three-dimensionally. We then place the cells on these cartridges and this actually shows the printer actually being initiated printing this three-dimensional kidney structure, this construct that you see here, one layer at a time. These are actually, of course, still experimental where we are using these for implantation purposes.

And then I am just going to share briefly with you now for 30 seconds this brief clip of a patient who received an engineered bladder. So you can see firsthand from this patient what he is thinking. This was just recently recorded.

[Video shown.]

Dr. ATALA. That was Lucas Masella. He is now 10 years out from having received his engineered organ. So you see for us the promise of regenerative medicine is not about the technologies we choose. It is about the ability for us to help our patients, and having innovation, the patent on intellectual property is an important part of this process.

Thank you, Mr. Chairman, Members of the Committee.

Mr. GOODLATTE. Thank you, Dr. Atala.

Dr. Fulkerson, I understand you have a demonstration for us of Rosetta Stone's latest language learning program. If you could take a moment to show us and I believe introduce us to your language coach.

Mr. FULKERSON. Thank you, Mr. Chairman.

So what I am going to show you is a quick introductory video that is the first exposure that our customers have when using Rosetta Stone v4 TOTALe to introduce the product to them. And then I will make a few comments at the end.

[Video shown.]

Mr. FULKERSON. As a technologist, this is embarrassing. [Laughter.]

Since we don't get to hear it, I will pause it and talk through the main part of our product.

The way Rosetta Stone works is we use pictures, sound, and text to convey meaning. So most language learning systems that you have used, going back to school, have always relied on translation where someone teaches you in the language that you already know about the language that you are trying to learn. At Rosetta Stone, we feel strongly that that just is not the right method. The right method is to try to immerse people in the language they are trying to learn and use those same cognitive processes that our children use to learn language as adults learning.

So we have set up situations, almost little puzzles, that give you a situation that you can start to see differences between pictures or hear differences between sounds, the same challenge that our kids do when they learn a language to try to figure out what is that new thing that mommy or daddy just said. My 5-year-old probably doesn't know what a microphone is, but if I were to say I'm talking in a microphone, he could figure out that this thing in front of me is probably a microphone and from context start learning. And that is exactly how Rosetta Stone works. So we don't rely on the crutch of translation. We rely on your own ability reason and to think and solve those sort of small, little micro puzzles, but as you do, you start feeling much more confident in your own ability to learn as opposed to memorizing things that are hard for us, even in our native languages, like grammar. Most of us probably don't look fondly on the days of learning English grammar, but that is how we try to teach people their second language or their third language. So the idea of immersing you in a way that feels fun and light and engaging is how Rosetta Stone works.

Our newest innovation that we call Studio is the idea that just using interactive software is better than most other methods to learn the language. You can start speaking. We have proprietary speech recognition that you can speak a substantial amount of time in our product. But talking to a native speaker is still invaluable. Having the opportunity—again just like our kids have the opportunity to talk to their parents and listen to their parents, that interaction with a native speaker is a critical piece.

But when you are very early in your language learning journey and you only know a small number of words, you know, 10, 20, 100 words, it is very hard to be successful. If I were to teach you 10 words of Portuguese and send you to San Paolo, you wouldn't think you could be very successful. But kids with a very small number of words can be successful. They can ask for something and get a response from their parent that starts making them feel confident and gain the confidence to try to use that language. And that is exactly what we have captured in Rosetta Studio. Rather than try to get you to finish your language learning journey, get you to the point that you know 2,000 words and can actually go to San Paolo.

We want you to feel successful very, very early, that sense that I can do it, I can learn a language because, to be honest, that has been the impediment for many of us learning a language is you feel you can't do it. You don't have a means to practice. You don't have a means to be successful. So the advent of Rosetta Studio and the ability from a business perspective to affordably provide native

speakers to language learners around the world via the Internet is an innovation that we rolled out in 2009 and then mass rolled out just last September across the U.S. to our consumer business and are in the process now of rolling out around the world. By the end of this year, it will be live in all of the Rosetta Stone offices in Japan, Korea, Germany, the United Kingdom, and hopefully by the end of the year China and Brazil.

Sorry about the technical problem.

Mr. GOODLATTE. Thank you very much.

We are going to have to recess in a moment to attend a joint session of Congress where the Prime Minister of Australia will address the Congress. We are required by our House rules to do so.

But you might use that opportunity to see if you can get that to work.

Dr. Smith, we will try to get your presentation in before we go.

Mr. SMITH. Okay.

[Video shown.]

Mr. SMITH. I am going to show you three different things. These are innovations that came out of my work at the University of North Carolina at Charlotte.

The first one is the technology that was used to replace sheet metal assemblies in aerospace applications with monolithic machinings. So in the top left, you can see an avionics tray that came out of the F-18. And on the left part of that figure, you can see the pieces that used to be assembled together from folded sheet metal components. And on the right, is the monolithic piece that was cut down from a solid. Now, you might think that we are throwing away a lot of aluminum, and that is true, but that is not where the cost was. The cost was in the hand labor and all the special fixtures and tooling that were required to do the assembly. The end result of this kind of a switch was huge. On the little avionics tray, it was a 73 percent reduction in cost. But all over the F18, Boeing estimates more than \$1 billion in savings in that program. Between the C/D model and the E/F model of the F-18, the plane got lighter and less expensive and cheaper, and getting all three of those together is really unusual.

So now the technology has spread over into commercial aerospace. So there are lots of parts like this on jumbo jets, for example. And you can see in the bottom picture this person is machining a cargo deck floor for the 777, and this thing is 10 feet by 5 and a half feet. It is about 5 inches thick. It starts out as a 2,500 kilogram slab of aluminum, and by the time the machining is all done, it is down 113 kilograms. The parts continue to get bigger and bigger because there is cost savings every time that happens.

Additionally, there are weight reductions because of the assembly. When you put together the sheet metal pieces, you have to have two layers of sheet metal and a fastener that goes between them. If it is monolithic, you don't have that. If the sheet metal pieces don't quite fit, then you have to put a shim into the space between them to make the fit tight. A typical jumbo jet has something on the order of 2,000 pounds of shims, and you carry those shims through the whole life of the aircraft. You pay a weight penalty, a fuel penalty the whole life of the aircraft. So we have a tech-

nology to make the machining of these monolithic components more accurate.

This one shows a concept. After the machining of something that is thin, we switch to a different tool which we use to push the thin parts around into a different configuration. So this part is about the size of my hand, and it is a heat sink. So a heat sink means that it dissipates the heat that something else produces, an electronic component, for example. So this has a lot of surface area, not much mass. It means it can dissipate a lot of heat.

Now, ordinarily something like this is relatively expensive and difficult to make. We made this in about 10 minutes on a relatively simple three-axis machine that most shops have commercially.

The last one that I will show you here is a technology that we developed for the breaking of chips. There are a lot of manufacturing operations that produce long, stringy chips in the cutting operation. We are shaping the metal from one size to another. As the metal peels off, it makes a long, stringy chip that gets tangled up on itself. And you can see in the pictures on the top left, the top right, the bottom left, these things often make a big snarl. They call it a bird's nest. Sometimes the operator is injured in trying to remove this. Sometimes the work piece is damaged. The sponsor for this was Oak Ridge Y-12, and their material is pyrophoric. It means it can catch on fire from the heat of the cutting. So the snarl is very dangerous.

What we did was to use the axes of the machine tool, the motion of the machine itself, to cause the chips to break, and this makes the chips break all the time. That is the photograph on the bottom left, just above the picture of the team. So this has applications across a wide variety of industries, including biomedical and plastics, in addition to the metal ones that I have shown you.

Mr. GOODLATTE. Thank you very much.

The Committee will stand in recess. We anticipate that we will reconvene at about 11:45 or sometime hopefully not too long thereafter. And we will take questions from the Members of the Committee at that time.

[Recess.]

Mr. GOODLATTE. The subcommittee will reconvene.

We will go now to our questions, and I will begin with a question for Dr. Fulkerson.

How important is brand protection and copyright enforcement to Rosetta Stone's business, and what proactive steps has your company taken to protect their products overseas and online?

Mr. FULKERSON. Thank you for that question, Mr. Chairman.

Obviously, in the technology world, especially in the consumer technology world, the power of your brand is in some ways as important as the quality of your product. It sets the initial expectation with customers of what they expect and what they are buying. So the power of Rosetta Stone as a brand is tremendously important. We spend a considerable amount of time protecting, both actively and sort of defensively, our product from both copyrighted type infringement where people would take our content, repurpose it in their own version of a software application. We also work very hard to protect just the software itself, in some cases actually to the detriment of our customers because we do things like put in ad-

ditional safeguards to lock the software, which is sort of a nuisance to customers, but we have to do it to make it harder for pirates to copy it and sell it.

And then I think the most egregious form that we see is people who just flat out pirate our software, who take the code that we have written, put it on their own CD's or DVD's, advertise it on search engines, and then sell it in some cases as our product even as Rosetta Stone. So it is not uncommon to find pirates often overseas who have taken our exact website, replicated it 100 percent, sitting on servers in a place where it is hard for us to reach them, and then selling what looks to be Rosetta Stone software, taking unsuspecting folks credit cards, sometimes delivering software, sometimes not delivering the software. But what we often find out when we get copies of that in, it is often not only a pirated copy but a copy that actually doesn't even work. So they are seriously hurting our brand from folks who get software that is actually broken.

I would say the amount of money that we spend to defend against that is money that we could be spending on other things. We could be spending that same money—the millions of dollars we are spending to protect that we should be spending on innovation and the next generation products, but instead we are spending that money on defense.

Mr. GOODLATTE. Taking that a step further, there is a general shift in the software industry from packaged software to cloud computing. Do you see the future of the software industry in cloud computing as a way to clamp down on piracy and push innovation to consumers at a much faster pace, or do you see it as a problem?

Mr. FULKERSON. As in everything, there is a little of both. I think in the enterprise computing space, people who are selling software to companies, cloud computing is sort of an immediate answer to provide better service. In the consumer space—and we are split. We have, obviously, customers that are large enterprises and customers that are consumers. Some of the cloud computing and the online and streamed kind of products are slower to be adopted by consumers. Consumers like the idea of buying it and having it, knowing they own it, and knowing if they change computers, they can reinstall it. But I think, as you point out, the trend is increasingly toward those kind of cloud computing initiatives.

I think the free services that we see in cloud computing, obviously, with explosive growth are a different case, but when you are actually trying to sell a product or sort of lease a product for a certain amount of time in a cloud environment, that is something that consumers, as of today, are not comfortable with. But as you also point out, it is a place where it is safer for us because when we control the servers and when it is very clear that we can sign those in a way that we can sort of validate that this is Rosetta Stone and our customers can come to our servers, it is much harder for folks to just flat out copy it. People will and there are famous examples of where people have copied and cloned cloud services also, but I think it is a much safer place and a place where if the consumers would appreciate it more and value that kind of service more, we would love to move in that direction.

Mr. GOODLATTE. Dr. Atala, you described this new field of regenerative medicine that uses a person's own reprogrammed stem cells. You mentioned in your remarks about how this could impact health care costs. What kind of new industries can you see developing around this field, and what steps have you taken toward commercializing your patents?

Dr. ATALA. So there are many areas that you can actually direct these therapies for. For example, a lot of these cells can actually be used to help with diagnostic tests. So you can actually use a patient's own cells with specific disease states. For example, you can take patients who have congenital disorders who have a gene-specific disease and pull cells and actually use those cells to help with diagnostic kits.

Another area where these cells can help is not just to use the cells to engineer organs, but actually just to inject them for therapy in the same patients. And there are many ways to do this. Some of the steps that we have taken to actually get this in the path is to actually get these technologies to patients. That is really the first step. How do we get these technologies to patients? Of course, we have to work very closely to go through the typical phase I, phase II, and phase III clinical trials that we need to go through with regulatory oversight by the FDA. After those clinical trials are done, then you can actually start to make that technology available to many other patients through industry. That is where these two factors come into play.

One is to make sure that we have the intellectual property necessary so that we can protect these technologies and to make sure that those patents are strong, that people can't contest those patents.

Second is to make sure that we get those technologies early, that we can assure that we have protection early with these technologies so we can go forward. And that is important because otherwise it is hard to get that kind of investment, especially when it is so costly.

And third, once we actually go through that process, the regulatory process is extremely important. And that is also something that really needs to be dealt with. We need to somehow help to streamline that process and then finally get those technologies out. I must comment, though, that the typical technology right now that goes through the FDA takes about 14 years, over \$1 billion.

Mr. GOODLATTE. So given that this work started in the mid-1990's, do you have developed technologies that are commercially available now, or are you still waiting on FDA approval? Or are you not to the point of even requesting FDA approval?

Dr. ATALA. Yes, we are through the FDA process now actually. We are currently involved with the FDA process in some of these technologies. Some are already commercial. Some of these regenerative medicine technologies are already commercially available, but some of them are still in the regulatory process, and that has been actually for two reasons.

One of them is that we did that on purpose to go slow. We have to go slow at first. So the patient that you saw, the clip that you saw earlier today, for example—we actually waited until we had an experience of up to 8 years of follow-up before we actually even

published the study. And the reason we did it slowly and carefully was because it was a new technology, and we really did not know what to expect long-term. There were many unknowns, but that was now in 1998 when we put that first technology in.

So now we can afford to accelerate the technology. We do not need to wait—to have a 5-year follow-up in all our patients like we did before. We can now afford to do this in a quicker manner and to actually translate these technologies in a more accelerated fashion because now we have tissues in patients, and there are many different clinical trials for over 14 years in some cases.

Mr. GOODLATTE. One more question. I will start with Dr. Smith and then turn to you, Dr. Atala.

As you have worked to commercialize your research, how important has the patent process been in securing funding and partnerships with larger companies and other entities?

Dr. ATALA. Extremely important, extremely important. Of course, one of the challenges that we have right now is the major backlog of the patents. So we have a lot of intellectual property that we are waiting to get a final result on. So that has actually been a challenge for us in the more recent years. All these applications that we have in, but not going through in an expedient manner.

Mr. GOODLATTE. Can you do the patent process and the FDA approval process at the same time, or does one have to begin before the other? How does that—

Dr. ATALA. Well, the challenge for us is that if you don't have intellectual property secured, it is very hard for investments to come in. So we need intellectual property so industry can trust that they will have something that will really give them the protection they need to go and make those large investments. So basically you can't have one without the other, which means that you really can't go and start treating patients necessarily through industry unless you have that protection.

Mr. GOODLATTE. Dr. Smith, what has been your experience?

Mr. SMITH. Well, certainly there is a lot of work that has to happen between the time that an idea has been shown as proof of concept, something that could be patented, and when a commercial product is created. There is a lot of work. There is a lot of expense that comes after the invention and before the commercialization. And the patent provides the protection to those investors. It draws the money to the idea because you know that you have protection for that hard work.

Now, certainly I will concur that the backlog in the patent office makes this difficult. But it is critical, especially to a startup company where the intellectual property is often the only tangible asset that the company has. The company is formed based on an idea, and it needs to draw the investment. And the patents are what makes that possible.

Mr. GOODLATTE. Thank you.

I will now turn to the gentleman from North Carolina.

Mr. WATT. I guess this is a variation or an extension of Chairman Goodlatte's question because I was going to ask you about your experiences with the patent office. Have they been good? I guess both of you all—all three of you possibly—have suffered the delay process. Is that correct? Is that true of all three of you?

Dr. ATALA. Yes.

Mr. FULKERSON. Yes.

Mr. SMITH. Yes.

Mr. WATT. Except for that, how have your experiences with the patent office been? Do you find them competent, I mean, well prepared to do it once they get to it?

Mr. SMITH. I will say in my experience the eventual outcome was often quite good. But the backlog is high. So the time to get to the outcome was long. And often the first review that we got was relatively perfunctory. It was more or less like a keyword search. And I think that this is because of the backlog. So the eventual result, after some responses from us to their reviews, was usually quite good, but the initial response that we got from them was often not satisfactory.

Mr. WATT. I guess if I followed Mr. Conyers' entreat, I should have been asking these questions in Spanish. [Laughter.]

So hablo espanol un poquito, muy poquito. So I am not going there. But that was for Chairman Conyer's benefit when he looks at the record. I did want him to know that if he were here and he were challenging me, I would compete with him. Gracias.

Dr. Smith, we have been hurtling down the road toward doing converting from a "first to invent" to a "first to file" system. I am led to believe that you have some wisdom to share with us on that. So let me allow you to get that wisdom into the record, and if either of the other two witnesses have either pros or cons to say about "first to file" versus "first to invent," I would like to hear whatever comments you have on that.

Mr. SMITH. Okay. I know that this is a somewhat controversial issue at the moment.

I will start by saying I think that the Constitution talks about protecting the rights of the inventors, and it seems to me hard to argue that the inventor is the one who filed first. I think the inventor is the one who made the invention. So that seems clear to me.

But beyond that, I would say that "first to file" tends to favor those organizations that have large patent staff on board, a large funding base and a large number of people to help prepare the patents because the motivation is to file quickly and often. So you file, file, file, file, file. I think it is disadvantageous to small companies, small universities, small inventors. I think particularly at the university level, I said that we need the protection of the 12-month grace period, and it seems difficult to reconcile the 12-month grace period with "first to file."

Mr. WATT. Any other comments?

Dr. ATALA. Yes. One of the challenges so that we can face with our patent system is that when you look at the patent system internationally, it goes through a "first to file." So in a way, we are not consistent with that system, and that becomes a little bit problematic when we go to the international arena because a lot of the patents that we file we are not filing just for U.S. protection but also for European protection and Asian, basically all over the world for the most part, and that in a way may put us at a disadvantage not to be in the same system of "first to file," which is the current system that is used pretty much internationally.

Mr. FULKERSON. I would add in the technology world I think things may be different than in manufacturing and biomedical where someone can grow a multibillion corporation that was started in the dorm room. That person sitting in their dorm room isn't thinking about the 5-year or the 6-year process and the tens of thousands of dollars to get a patent. They are trying to get their product to market. And so I think the initial Rosetta Stone innovations don't have adequate intellectual property protections in some ways. At this point, it is moot. But at the time, our Founders were trying to get products to market and were trying to raise capital by selling and raise revenue by selling products. So I think in that situation, clearly we would not have had a filing advantage.

I believe there is a problem right now with our patent system with the concept of trolls, folks who aren't making products. They are trying to generate revenue through the courts with patents. I think "first to file" makes that worse. You will have folks that are trolling to file first, not innovators, not product companies. So I am envisioning what could happen, but to me that is a dangerous situation.

Mr. WATT. Except for shortening the backlog and speeding up the process, are there any other specific procedural changes that either of the three of you would suggest to improve the patent process?

Mr. SMITH. Okay, I will go.

Mr. WATT. All right.

Mr. SMITH. Certainly there is an issue that in the current law it is one-size-fits-all, and yet there is a range of different kinds of products which are being patented. So some of them like software have relatively short lifetimes, and some of them like medical products have relatively long development cycles. So in one case the lifetime of the product expires before the patent is even examined, and in another case the patent protection expires before the product comes to market. And so certainly some kind of a recognition of this variation in the products which are being patented might be useful.

I would also say in the current fee structure, there is a two-tier system. So even the lower tier is still prohibitive for many small entities. Maybe there is a possibility for a third tier, a micro-sized company.

Dr. ATALA. I would have to agree with Dr. Smith that in terms of biotechnology, it does take longer to develop these technologies, and it does take longer to go through the process of trials. So I do agree with the statement that Dr. Smith made in terms of the length of the patents.

One of the challenges is to be sure that one's patents do get issued, that one is certain that we can assure the inventor that the invention is actually true, that we can actually retain that patent as being one that is solid in terms of its claims. And that is certainly a challenge these days in many areas that we experience where patents are being challenged and other types of procedures are being done. So it would help us tremendously to assure that the patents that in fact are issued are solid and true to what they represent.

Mr. WATT. Dr. Smith, it seems to me that in—well, even I guess all three of you—possibly there would be some consideration of

prior art, if you are basing what you have done on somebody else's invention, research. How has that been a factor in the way you have proceeded?

Mr. SMITH. Certainly when we prepare a patent application, we try to disclose the prior art. We disclose everything of which we are aware. And when the examiner examines the patent, they look for additional prior art that we might not have been aware of. Yet, this is a really tall order for the examiner. How can they be aware of all of the trade journals, all of the publications, all of the places where the prior art might have appeared? It is a demanding task. And I think giving third parties the ability to submit written documentation about a patent which has been published but not yet granted would be useful. Essentially you get interested parties assisting the patent office in finding the relevant prior art.

Mr. WATT. Finally, I don't see lights up there, so I am kind of wondering here.

The technology transfer from the research to the commercialization of it is always a challenge there for universities in particular. Is there some way we can streamline that to make it clearer, or is it just a different case for every technology commercialization and just too hard to develop a set of rules for?

Mr. SMITH. Well, certainly I will say that it is helpful that the university can own the intellectual property even though the research might have been funded by an agency of the Federal Government, for example. The tech transfer office at our university is motivated to try to get those technologies commercialized. We view that as one of our key missions at the university to get the research work out into commercial practice.

Dr. ATALA. In terms of the technologies that we develop, it is very important that we continue with the protection from the Bayh-Dole Act. It is critical because that actually allows us to do the research with national initiatives, programs which are designated by the Nation to be of great need. And if we didn't have that ability, we would then be relying mainly on just special interest of specific groups to actually pursue that research.

Mr. WATT. The Senate has passed a bill, and we may be calling on you all's technology transfer people to take a closer look at what they have proposed and what may or may not be in the House version of the bill. So I may be calling on—it is nice to have experts I can call on, though. So I appreciate you being here.

Mr. Chairman, I will yield back the balance of my time.

Mr. GOODLATTE. I thank the gentleman.

It is my pleasure to recognize the Ranking Member of the full Committee, Mr. Conyers from Michigan.

Mr. CONYERS. Thank you, Chairman Goodlatte.

Can we get a credit for medical school for the performance and the work that was offered here today?

Mr. GOODLATTE. It will be part medical and part law school. [Laughter.]

Mr. SMITH. Some engineering.

Mr. CONYERS. Dr. Atala—

Mr. WATT. I wanted you to know that I challenge you to do your questioning in Spanish.

Mr. GOODLATTE. Right and your tests will be in Spanish too.

Mr. WATT. I did mine in Spanish.

Mr. CONYERS. I should have expected——

Mr. WATT. You issued the challenge. I rose to the occasion in your absence.

Mr. CONYERS. Thank you.

You mentioned heart disease and diabetes as things that we need to pay more attention to, but what about cancer where treatment is given more attention than prevention?

Dr. ATALA. Absolutely. Well, I think that is where regenerative medicine really has a role, a very special role, because currently if you think about disease, most of the time you are not aware that you have that problem until your organ is very far gone. I will give you an example. You may be playing tennis once a week, and you have never experienced any problem. Yet, one day you play tennis and right after you get chest pain. You go to the doctor's office. They do an arteriogram and they find out that your vessel is now over 90 percent occluded. Interestingly, that is when you start having symptoms, once you are over the 90 percent range. You didn't have that pain when your vessel was 70 percent occluded or even 80 percent occluded. So regenerative medicine has the ability to actually start treating you much earlier. By prevention, by you being more aware of your body's functionality over time, you may be able to prevent that end stage part of your disease by picking up these diseases early and addressing them earlier.

Mr. CONYERS. Now, what about the annual checkup? Does that give us any consolation?

Dr. ATALA. Well, you know, the annual checkups that you go through are good and they are certainly something that should be done, but the challenge is that doing a 360 analysis of your body currently is not necessarily economically feasible or possible because it is so complex. And so I think a lot of the work that is being done currently with genetics where we will be aware of what your genetic predisposition is based on your genome so we can actually take a small sample of your saliva, for example, and do a genome analysis where we know what your traits are, what genes are you expressing. We can then take those genes and start correlating to disease, and we will know what you are prone to get. And now we can start focusing in those specific areas based on your family history and your own genetic code and start preventing diseases that you are more prone to have.

Mr. CONYERS. Well, I don't want to get too personal but Mel Watt and I both try to play tennis at this stage of our life, and what I am interested in is that at the 90 percentile, before we get a little heartburn after tennis, you are telling me, in effect, that the annual checkup will not have us discover that before we get to this very advanced circumstance.

Dr. ATALA. Yes, that is correct. Not all the time. that is the challenge and that is why people come with a chest pain when they do with heart disease. I mean, that is the challenge. And really, the only way to do that—let us say we want to look at your blood vessels. I mean, you have to go through an arteriogram. So your heart disease and your symptoms is what really prompts the physician to do that.

So that is why prevention is so important, and regenerative medicine really does play a major role in that because you have the capacity to actually hold off disease when you first detect it. And so better detection and better prevention are totally part of what regular health care should be.

Mr. CONYERS. Could I get a couple minutes more, Mr. Chairman?

Mr. GOODLATTE. Without objection.

Mr. CONYERS. Thank you.

Dr. Fulkerson, we will be holding a hearing Monday on rogue websites and the piracy and so forth. I hope that you will be able to follow that along with us and give us your subsequent comments and recommendations as a result.

Now, we have got some legislation called “Combating Online Infringement and Counterfeits,” and we are trying to get that through to stop pirates from getting payment. Your comments?

Mr. FULKERSON. I am not familiar with that exact piece of legislation. But the problem of rogue websites—both their existence and the ease that they are found are things that I think that your subcommittee—we would welcome you to think about those problems.

Related to the intellectual property side, the patent reforming law gets a lot of attention. The trademark law and policy, which ends up making it easier for these rogue websites to be discovered through search engines, is something that we would also love the subcommittee to think about, which is all terms in a search engine aren’t equal. Some of those terms are trademarks. And when someone types in a trademark’s term, that’s not just like typing anything else. It has special protections in most cases under our laws. But trademark law and policy hasn’t caught up in my opinion to the modern use of search engines and trademarks. That makes it easy for consumers to both find and to be duped by those rogue websites. It makes it very easy to type in a term and, bang, you are on a site which you may think is the owner of that trademark where in fact it is a bunch of people in the back of an alley in a place that isn’t Harrisonburg, Virginia. So that is something that we would love to see legislative action and investigation from your Committee.

Mr. CONYERS. Dr. Smith, “first to file” is something that businesses and foreign companies recommend, but universities and small businesses and garage-type inventors are less enthusiastic about it. What are your comments?

Mr. SMITH. Well, certainly “first to file” provides clarity, and clarity is useful in drawing investment to a company. I understand that. I also hear the argument that “first to file” would harmonize our patent law with the laws of other countries. I don’t find that argument particularly compelling. Certainly there are countries that don’t respect intellectual property at all, and we don’t want to harmonize our law with them. So I think the issue is protecting the rights of the inventor, and clearly the inventor is the one who created the invention.

I will say I think there is also an issue that “first to file” encourages frequent filing of patents that may be of lower quality than if you have time to develop the idea more fully. So I think it makes the problem of the backlog at the patent office worse.

Mr. CONYERS. Is there anybody here more enthusiastic about “first to file” among the witnesses?

Dr. ATALA. Well, I mentioned that one of the challenges that we have is that if we are not consistent with the international system, that may place us at a disadvantage.

Mr. CONYERS. Thank you very much, Mr. Chairman.

Mr. CHAFFETZ [presiding]. Thank you.

I want to talk, Dr. Atala, about—can you walk us through the Armed Forces Institute of Regenerative Medicine’s most immediate research goals, and are there companies that you are currently partnering with?

Dr. ATALA. Yes. The Armed Forces Institute of Regenerative Medicine is really an effort to bring together the best technologies that we have for our wounded warriors, and this is in one of four major categories, five areas but four major categories, which include burns, craniofacial injuries, limb and digit injuries, including compartment syndrome, and scarless wound healing. And it really brings together over 30 institutions with every branch of the military supporting this effort to bring these technologies faster. And we are developing technologies right now for our wounded warriors. The goal of AFIRM was to actually have one technology ready for our patient before the 5 years of the initial program were completed. We are now basically just starting year 3, and we have 15 clinical trials currently at some stage of development.

Mr. CHAFFETZ. What do you see happening with jobs? Assuming that everything continues to progress to the optimism that we all hope that this happens, what is going to happen to the job market in this sector, if you are able to have that success?

Dr. ATALA. Hopefully that will increase markedly. And so by having all these technologies at the clinical trial level, we already have many commercial partners which we are bringing into the Armed Forces Institute for Regenerative Medicine, and these commercial partners together with AFIRM investigators being able to bring these technologies to industry so that these products can be manufactured here in the U.S. and thus increase jobs and create jobs for our citizens.

Mr. CHAFFETZ. Dr. Fulkerson, your company, Rosetta Stone, is truly a global company. Tell me about your experience internationally, what market access problem/challenges that you face, the competitive markets that you are feeling, and how that relates to what we are talking about here today.

Mr. FULKERSON. Thank you. Sir, right now we have offices in four countries internationally and are considering expanding in others. Unfortunately right now, some of the world’s largest language learning markets are countries that do have notoriously high piracy rates and, in some cases, as we just talked about, disrespect for intellectual property. And so even though those are tremendously very large markets for us, the risk and the burden of trying to enter those markets such as China is one that—we would love to have been there already, but those obstacles have kept us from going.

Mr. CHAFFETZ. But are you selling any product in China?

Mr. FULKERSON. We say we are huge in China but we don’t generate any revenue in China.

Mr. CHAFFETZ. Do you have anything to quantify the pervasiveness of the problem in China?

Mr. FULKERSON. It is hard to quantify. We could certainly send you photographs of Rosetta Stone-looking kiosks in Shanghai that aren't run by Rosetta Stone, and it is not Rosetta Stone—

Mr. CHAFFETZ. So how do you follow through on that to make sure—I mean, you are a company. You got employees. You are trying to do the right thing and somebody is taking your brand, your product, selling it in China. What do you do? Who do you call?

Mr. FULKERSON. It is a great question. In China, there is very little that we can do. Working with U.S. Customs and ICE here in the United States—and they have been very helpful in helping us intercept pirated goods coming in.

Mr. CHAFFETZ. So what do they tell you when you say, hey, look we got a problem in China? What do they say?

Mr. FULKERSON. I am on the technology side. I should get someone else to answer the specific question of what kind of responses we get. But my impression, my layman's impression, is that they basically say there is not much they can do, but they will petition the Chinese Government. They will send letters, but my belief is that those are just ignored.

Mr. CHAFFETZ. Well, that would be interesting. I would love to follow up how a company who is starting to be successful—how they follow up with the enforcement side of things, not just for the importation but what is happening in other markets, China and others. It is not just China, but certainly that is the one that you continue to hear time and time again.

We have just a few seconds. Dr. Smith, tell us just in the briefest words—we always talk about getting more kids engaged and interested in engineering. How do we do that?

Mr. SMITH. I think you have to show them something exciting. There are plenty of exciting activities at our university. We have a big tour program. We bring students through a lot. Motor sports, for example, is a big draw in North Carolina, and a lot of students come through our motor sports shop. I think you have to show them something exciting, a real, tangible product.

Mr. CHAFFETZ. Thank you.

My time has expired.

We will now recognize the gentlewoman from Texas, Ms. Jackson Lee, for 5 minutes.

Ms. JACKSON LEE. Let me thank the Committee very much for this hearing.

Let me just, across the board, ask Dr. Fulkerson, Dr. Atala, Dr. Smith, how many jobs can this kind of technology create in America. Just give me a wide range. And do you consider this kind of technology or technology, period, sort of the work generator of the 21st century?

Mr. FULKERSON. I think the easy answer is it is unbounded. I think as we become more and more an information society and we grow more and more information workers, all Americans at some level are potentially engaged in information work. I think we have specific numbers in my written testimony from the Business Software Alliance of exactly how many jobs in which type of industries. But I believe from a growth perspective, technology has been a

major driver of growth, obviously, in the last 30 years, but whether that is just pure information, computer technology, or any of the other—

Ms. JACKSON LEE. But jobs could grow every year. You can see jobs growing every year with technology inventions.

Mr. FULKERSON. Oh, yes, ma'am.

Ms. JACKSON LEE. Dr. Atala?

Dr. ATALA. The same. In the field of regenerative medicine, basically you have an increasing number of technologies that are being used in terms of experimentally, a large number of companies which are currently formed for the field. And we do expect—as I had mentioned earlier, the current global market for this field is estimated to be in the vicinity of \$118 billion just by 2013.

Ms. JACKSON LEE. And you are an American-based company. So you are generating \$118 billion that would impact creation of American jobs and investment in America. Is that correct?

Dr. ATALA. Well, I am actually at the Wake Forest Institute for Regenerative Medicine which is a nonprofit part of Wake Forest University in Winston-Salem, North Carolina.

Ms. JACKSON LEE. Right. I am aware of that, but out of that would come enormous amount of commercial or private sector jobs or investment.

Dr. ATALA. That is right. One of the major benefits is to be able to keep these technologies here, keep the innovation here in the U.S., manufacture the technologies here, and create jobs here.

Ms. JACKSON LEE. Thank you. I want to hear more, but my time is short.

Dr. Smith, how many jobs do you think out of this kind of arena could one create in the 21st century?

Mr. SMITH. Well, for the technologies that I showed, the number of jobs that were directly created are at the moment small. These are start-up companies. But because the technologies that I showed are directed specifically at productivity, the number of jobs that are created is quite large.

There is a lot of talk about the manufacturing sector in the United States having trouble competing internationally with the wage difference. And I think that is the wrong question. I think the right question is given that there is a wage difference, how do you remain competitive, and I think the ways that you remain competitive are you innovate, you make things that other people can't make, you improve your productivity. If you want to maintain a wage difference, you have to maintain a productivity difference. I think if we get it right, what would matter is proximity to market more than the cost of the labor.

Ms. JACKSON LEE. We need to market what our best talents are.

Let me ask my two questions so that you can be in the middle of answering if my time runs out.

First of all, we all know as kids, when you heard a shriek on the playground, it was somebody saying you are not playing fair, or maybe when you heard a little rumble in the back yard somebody was not playing fair. I abhor an uneven playing field. I think it is just ludicrous.

So I need you to tell me with your greatest passion, even though, Dr. Fulkerson, you said that is not your area, what Congress can

do to stop this piracy and this stealing of intellectual property. Just give it to us from your gut.

Dr. Fulkerson, I just want to know can I learn Spanish, French, and anything else. How long will it take me on the Rosetta Stone? [Laughter.]

Ms. JACKSON LEE. But my last point, Dr. Atala, if you could tell me whether or not you have got any partnerships or are working with any minority and women doctors, researchers, and scientists and cultivating any small businesses from the minority and women-owned business community.

But if you could quickly go on what Congress can do to stop this.

Mr. FULKERSON. We obviously have to continue enforcement of the folks who are actually doing the piracy. But I continue to believe that the single biggest thing we can do is make it harder to find the pirates.

Ms. JACKSON LEE. Make it?

Mr. FULKERSON. Make it harder for consumers to find the pirates. If a pawn shop was selling pirated goods, local police will shut that down. If an international search engine is making it easy to find pirated sites, there is no way to shut that down. They will cooperate at times, but it is just too easy for pirates to get into our living rooms, to get into our laptops, and sell us stuff. I believe in a free Internet, but there are things we need to do around trademark enforcement and protection to make that harder.

Also, I would like to just add—I can get you the job number. The Business Software Alliance, of which we are a member—and we can provide you this information—estimates that in the U.S. over the next 2 years, we will create 282,000 jobs in information technology.

Ms. JACKSON LEE. Excellent.

Dr. Atala?

Dr. ATALA. Yes. As part of the institute, we are proud to report that we have people that come with us from 23 different countries and many nationalities and many different minority groups. So that has been a good thing for us.

When we do the clinical trials actually, we have to abide by all the regulations in terms of making sure that all patients also participate in the clinical trials.

And when it comes to industry, of course, again we are not connected at that level with industry as part of my role at the institute, but when we do commercialize these technologies and we do bring these technologies to a commercial venue, we certainly make sure that all of the appropriate rules are followed in that direction.

Ms. JACKSON LEE. Dr. Smith? Stop piracy.

Mr. SMITH. Stop piracy. This is difficult. I mean, I think it is even difficult inside of the U.S. If you are a small company and you believe that you are being infringed, it is often difficult to prevail because you don't have the funds that are required to last long enough in court. And I think overseas this is even a more complicated problem.

In regard to your question about minorities, one of the most successful start-ups spun out of UNC Charlotte by my graduate student actually is a female-owned company.

Ms. JACKSON LEE. Excellent.

Thank you, Mr. Chairman. I thank all of you.

Mr. CHAFFETZ. Thank you.

At this time, we are going to draw a conclusion to this hearing. We appreciate all the time, effort, and resources that you take to be here. We truly do appreciate your making time for the Committee and offering your expertise. And at this time, the Committee stands adjourned.

Oh, yes. I would make a note for the record that all Members will have 5 legislative days to enter information into the record, and we also extend that to you. If you have additional comments or things that you would like to see inserted into the record, we allow for 5 additional days.

And with that, I thank the witnesses and the Committee will stand adjourned.

[Whereupon, at 12:48 p.m., the subcommittee was adjourned.]

