COOPERATIVE RESEARCH AND TECHNOLOGY ENHANCEMENT (CREATE) ACT OF 2003

HEARING

BEFORE THE

SUBCOMMITTEE ON COURTS, THE INTERNET, AND INTELLECTUAL PROPERTY

OF THE

COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

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COOPERATIVE RESEARCH AND TECHNOLOGY ENHANCEMENT (CREATE) ACT OF 2003

TUESDAY, JUNE 10, 2003

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

The Subcommittee met, pursuant to notice, at 10:08 a.m., in Room 2141, Rayburn House Office Building, Hon. Lamar Smith (Chair of the Subcommittee) presiding.

Mr. SMITH. The Subcommittee on Courts, the Internet, and Intellectual Property will come to order. This is a hearing on H.R. 2391, the Cooperative Research and Technology Enhancement (CREATE) Act of 2003. I will recognize myself for an opening statement and then the Ranking Member. All other opening statements, without objection, will be made a part of the record and then we will look forward to the testimony from our witnesses today.

The stunning success scientists achieved in rapidly identifying the cause of Severe Acute Respiratory Syndrome (SARS) is a recent example of how unprecedented collaboration among Government and private labs can save lives and protect the public's well-being. The reaction to the SARS virus illustrates that in an increasingly connected world, it is necessary for our public and private organizations to adapt to new challenges and develop new ways of doing business.

Understanding this, Congress enacted a series of patent laws and amendments in 1984. One of these amendments, codified in 35 U.S.C. 103(c), created a safe harbor for inventions that were the product of a collaboration involving co-inventors within a single company. The amendment changed the U.S. patent system to reflect the manner in which companies actually conduct their internal research activities.

The legislative history makes clear that Congress intended to discourage individuals from attempting to use non-public information, also known as "secret prior art," to challenge the issuance or validity of a patent where co-inventors voluntarily exchanged confidential information concerning a prior invention developed by one or more of the research partners. What the legislative history leaves unclear and significantly what we are here to explore today are the arguments for and against expanding the secret prior art exemption to collaborations involving researchers at more than one organization.

Unlike 1984, today's biotech, pharmaceutical, and nanotechnology companies conduct much of their research with partners such as universities or other public or private organizations. Solving any complex biotech problem requires the integration of numerous disciplines and the involvement of scientists, engineers, and researchers who are located at multiple organizations. Anything that discourages open communication or causes a chilling effect among researchers is likely to prevent or delay vital research. Critics of the Federal Circuit's 1997 *OddzOn* decision believe its effect has, in fact, been negative.

The patent system serves the public best by promoting innovationg, encouraging communication among researchers, and removing barriers to patents. Recognizing the need to adapt the patent law to this new research paradigm, the Ranking Member, Mr. Berman, and I introduced H.R. 2391, the Cooperative Research and Technology Enhancement (CREATE) Act of 2003, along with nine cosponsors, most of whom are Members of this Subcommittee.

The CREATE Act's purposes are, one, to promote communication among team researchers located at multiple organizations; two, to discourage those who would use the discovery process to harass coinventors who voluntarily collaborated on research; three, to increase public knowledge; and four, to accelerate the commercial availability of new inventions.

Last year, the Subcommittee conducted an oversight hearing on the topic. The legislation discussed today addresses concerns raised at that hearing. We are fortunate to have excellent witnesses with extensive experience relating to the intersection of patent law, cooperative research, technology transfer, and biotech issues, and we certainly look forward to their testimony.

The Ranking Member, Mr. Berman, is recognized for his opening statement.

Mr. BERMAN. Thank you very much, Mr. Chairman, and I thank you for taking up this issue and moving ahead so forcefully.

There is no question that research collaborations are a key element to the success of the U.S. economy. As some of our witnesses will detail today, such collaborations are also key to curing many life-threatening diseases. So Congress should do all in its power to provide an environment in which researchers have the freedom and the opportunity to develop inventions and new ideas.

At a hearing in March of 2002, this Subcommittee learned that a judicial interpretation of U.S. patent law threatened to chill certain types of research collaboration. Witnesses at that hearing decried the Federal Circuit decision in *OddzOn Products* v. *Just Toys* as chilling the informal inter-institutional collaboration that is increasingly important in today's complex, resource-constrained research environment.

The *OddzOn* decision held that information qualifying as prior art under Subsections 102(f) or 102(g) of Title 35 can be used to dismiss a patent application as obvious. This dismissal can occur even if that information was confidential, shared among consenting parties, or undocumented. An otherwise patentable invention can't be denied a patent simply because research partners have exchanged information. This undoubtedly can cause a chilling effect on collaborative research.

What makes this particularly troubling is that it affects research universities and nonprofit institutions much more than it does private companies. For some entities, there may be ways to maneuver around the threat of 103(c) by creating a joint venture or by assigning intellectual property rights to a single entity. However, many State and Federal Government organizations cannot assign rights to an outside partner due to their established laws and practices. Public research institutions may not have the means to circumvent the potential problems of 103(c).

The original intent of that section was to promote teamwork and to stimulate collaborative work. When we amended the Patent Act in 1984, we were careful to allow for the disclosure of information among collaborators within the same organization. The research paradigm then was one in which collaborations across institutions was a rarity and we apparently neglected to include this possibility in the language of Section 103(c). Thus, the *OddzOn* decision is not an incorrect interpretation of the law, it is a correct, if unfortunate, reading of that law.

So I think the Subcommittee should adopt legislation to address the negative consequences of that decision and I think H.R. 2391 is a good starting point for such legislation. While I understand H.R. 2391 may require some tinkering, I commend the Chairman for getting the ball rolling by introducing it now.

At the same time, I don't want to downplay concerns about possible unintended consequences created by the language of the bill. I have heard such concerns from a variety of credible quarters and I hope that our witnesses today will address some of their concerns, and if they are valid, I believe we should redraft H.R. 2391 to accommodate them. I am certain the Chairman will attempt to accommodate all reasonable concerns as he has consistently done on all other legislation.

In conclusion, Mr. Chairman, I commit to work with you on legislation to overturn *OddzOn* and promote research collaboration and I look forward to hearing from the witnesses on whether H.R. 2391 or some variation thereof is the proper vehicle for doing so. I yield back.

Mr. SMITH. Thank you, Mr. Berman.

Our first witness today is Dr. Jon Soderstrom, the Managing Director of the Office of Cooperative Research at Yale University and the Vice President for Public Policy at the Association of University Technology Managers. At Yale, Dr. Soderstrom is responsible for managing the intellectual property created at the university to achieve the maximum benefit for the public while providing a financial return to support the university's research efforts. Dr. Soderstrom is a past President of the Association of Federal Technology Transfer Executives. He received his Ph.D. from Northwestern University and his A.B. from Hope College.

Our second witness is Eric Steffe, a partner and patent attorney at Sterne, Kessler, Goldstein and Fox in Washington, DC. Mr. Steffe was among the first to highlight the *OddzOn* case as presenting significant problems for research entities engaged in collaborative research with an industry partner. A graduate of the George Mason University School of Law, he has a master's degree

in molecular biology and a bachelor's in physics from the University of Georgia.

The next witness is Jeffrey Kushan, a partner and patent attorney at Sidley, Austin, Brown and Wood's Washington, DC office. Earlier this year, American Lawyer magazine named Mr. Kushan as one of the top 45 lawyers in the United States under the age of 45. Mr. Kushan was selected recently to be the next Chairman of the American Bar Association's Patent Law Committee. Mr. Kushan is a graduate of George Washington University Law School. He earned a master's in chemistry from the University of North Carolina at Chapel Hill and a bachelor's in chemistry from the College of William and Mary.

I wonder if American Lawyer is going to do a top 46 when you are 46? I don't know. [Laughter.]

Our final witness is John Thomas, a professor of law at Georgetown University, where he specializes in intellectual property licensing, international intellectual property law, and patents. Professor Thomas has served as an instructor at the Patent Academy since 1997 and as a visiting scholar with the Congressional Research Service since December 1999. Professor Thomas earned an L.L.M. from George Washington University Law School. A magna cum laude graduate of the University of Michigan Law School, Professor Thomas possesses a B.S. in computer engineering from Carnegie Mellon University.

Welcome to you all. Your entire testimony will be made a part of the record, but we do ask you to limit your oral presentation to 5 minutes.

With that, Dr. Soderstrom, we will begin with you.

STATEMENT OF JON SODERSTROM, PH.D., MANAGING DIRECTOR, OFFICE OF COOPERATIVE RESEARCH, YALE UNIVERSITY, NEW HAVEN, CT, ON BEHALF OF THE ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS

Mr. SODERSTROM. Mr. Chairman, thank you for the opportunity to testify before your Subcommittee on the important topic of promoting research collaborations. My name is Jon Soderstrom. I am the Managing Director of the Office of Cooperative Research at Yale University. My office is the technology transfer organization for Yale.

My statement today is being made on behalf of Yale and the Association of University Technology Managers, known as AUTM, for which I serve as the Vice President for Public Policy. AUTM is a nonprofit society of academic technology transfer professionals entrusted with the management of intellectual property with more than 3,000 members now representing over 1,500 institutions and companies across the globe.

It is well known that industry depends heavily on collaborations with universities for basic research. In the pharmaceutical, biotech, and high-technology areas, America's universities are the engines for generating the cutting-edge ideas that have kept this country's industry as world leaders. Public funding of university research and the encouragement of collaborations among scientists at public, private, and nonprofit entities have been keystones of the United States's strength and leadership in these sectors.

At Yale, we have seen the profound and positive effect upon the welfare, health, and safety of humankind that results from collaborative relationships. Our researchers, together with their collaborators at other institutions, have played significant roles in developing two key ingredients of the so-called AIDS drug cocktail, the reverse transcriptase inhibitors d4T, known commercially as Zerit, and 3TC, known as Epivir. These medicines have fundamentally changed the nature of AIDS therapy during the past decade.

One of these researchers, Dr. Yung-Chi Cheng, has worked to develop drugs that work against AIDS with less harmful side effects. As many of you are no doubt aware, long-term usage of anti-AIDS drugs can cause problems in nerves, the pancreas, and the liver. One such drug turned out to be 3TC. Originally synthesized by a Canadian researcher and identified as an anti-viral agent, samples were sent to Dr. Cheng for study of the drug's toxicity. Working with other collaborators at Emery University in Georgia, he found that one form of 3TC in particular, when used in combination with AZT, the only known drug at the time, not only reduced the side effects, but also increased 3TC's efficacy in combatting the AIDS virus.

This is but one example of the life-changing discoveries resulting from our scientific collaborations. Currently, Yale has eight novel therapeutic drugs being tested in 13 different clinical trials for treatments of such life-threatening diseases as various types of cancer, Hepatitis B, and AIDS. The benefit to the public derived from these and other inventions created through our research together with other academic research institutions is incalculable.

The success of bringing these and countless university inventions to the marketplace has depended on rich collaborations among scientists within the university, collaborations among scientists at different universities, and collaborations among university and industry scientists. Collaborations among scientists and husbanding research dollars makes good sense for the cost and complexity of research today, especially with various institutions engaging in essentially the same technological areas.

Moreover, the evolution of science has made interdisciplinary research more and more common and, in fact, essential if solutions to complex problems are to be found. The recent stunning example of SARS is but one of many.

With the bulk of university research being supported through Federal grants and contracts, to be prudent with taxpayer monies, it makes good policy sense to encourage collaborations among scientists for public interest. These collaborations between scientists at separate universities and between industrial and university scientists often result in joint inventions. In fact, there have been an increase in the number of these collaborations and today, Yale has over 100 inter-institutional agreements which reflect just that.

In spite of the trend toward scientific collaboration and the economic practical necessity for such collaborations, the recent decision of the U.S. Court of Appeals in the *OddzOn* decision threatens to discourage just such collaborative activity. We are seriously concerned about the implications of this decision. The decision, while accurately interpreting the law, nonetheless creates a significant threat for the loss of intellectual property rights for inventors who

engage in joint research and development projects with scientists not employed by the same institution.

The implications of the *OddzOn* decision are significant. Researchers who enter into a well-defined and structured research collaboration but who do not first enter into a contractual agreement to transfer their rights to a single entity can create obstacles to obtaining or enforcing a patent on an invention that arises out of the research collaboration. This decision creates significant problems due to the very nature of collaborative research and development projects among universities, Government labs, and industry.

The unhindered flow of information among researchers within these collaborations is essential to the conduct of research and crucial to successful outcomes. Laws and policies that have the effect of impeding the flow of information among researchers will, for obvious reasons, have a stifling effect on the progress and success of such projects.

We support efforts that will help to remedy undesirable impediments to collaborative research created by the *OddzOn* decision. This will ensure more efficient development of products, utilizing tax-supported research results and an increase in the transfer of technology for the public good.

Thank you, Mr. Chairman.

Mr. SMITH. Thank you, Dr. Soderstrom.

[The prepared statement of Mr. Soderstrom follows:]

PREPARED STATEMENT OF E. JONATHAN SODERSTROM

Mr. Chairman, thank you for the opportunity to testify before your Subcommittee on the important topic of promoting research collaboration.

My name is Jon Soderstrom. I am the Managing Director of the Office of Cooperative Research (OCR) at Yale University. The Office of Cooperative Research is the patent management organization for Yale University. My statement today is being made on behalf of Yale and the Association of University Technology Managers known as AUTM for which I serve as the Vice President for Public Policy. AUTM is a nonprofit organization created to function as a professional and educational society for academic technology transfer professionals involved with the management of intellectual property. AUTM was founded in 1974 as the Society of University Patent Administrators. That group laid the foundation for the association that exists today—more than 3,000 members strong representing over 1,500 institutions and companies across the globe. Neither Yale nor AUTM have received any federal grants, or engaged in any federal contracts or subcontracts that require reporting under House rules.

YALE'S EXPERIENCE

Yale's Office of Cooperative Research was created in 1982 in response to the passage of the Bayh-Dole Act that encouraged universities to seek commercial partners to move their discoveries out of the laboratory and into the marketplace. The Bayh-Dole Act allows academic institutions to retain ownership of inventions resulting from federally funded research and to manage the licensing of them to industry for commercial product development in the public interest. The fundamental thrust of the Act was to change the presumption of title to any invention made in whole or in part with federal funds from the government to the universities, other non-profit entities and small business. Prior to the Act, the Government owned the inventions and had responsibility for licensing them. Government policy at that time, was generally to offer non-exclusive licenses under all inventions which it owned—a licensing stance administered under some 24–26 different non-uniform agency policies, which proved to be highly unsuccessful. Since the passage of the Bayh-Dole Act numerous pharmaceutical and medical products, environmentally friendlier manufacturing technologies, inventions which improve public safety, and information technology services have resulted from the transfer of federally supported research results from academic laboratories to the business community and, ultimately, consumers. In many instances, these products and processes would not have reached

the public without the incentives and procedures afforded to higher education institutions by the Act.

The OCR was charged with extending and expanding Yale University's interaction with the private sector. The duties of the OCR include oversight for patenting and licensing activities, as well as development of university inventions. OCR staff work with Yale researchers to identify inventions that may ultimately become commercial products and services useful to the public. OCR staff also helps create industrial partnerships to develop Yale inventions.

Yale technology transfer successes have had a profound and positive effect upon the welfare, health and safety of humankind. Researchers in the Department of Pharmacology of the Yale School of Medicine, for example, together with their research collaborators at other institutions, have played significant roles in developing two key ingredients of the so-called drug cocktail: the reverse transcriptase inhibitor d4T, known commercially as Zerit, and 3TC, known as Epivir. These medicines have fundamentally changed the nature of AIDS therapy during the past decade.

William Prusoff, Ph.D., Professor Emeritus of Pharmacology, has spent a 45-year career at Yale investigating potential antiviral and anticancer compounds, part of the traditional, small-molecule approach. In the late 1950s he synthesized idoxurine, an analog of thymidine, which was the first antiviral compound approved by the FDA for therapy in humans. It was used to treat herpes infection of the eye. Dr. Prusoff and his long-time collaborator, the late Tai-Shun Lin, Ph.D., discovered in the 1980s that a thymidine analog, reported in scientific literature by researchers from Wayne State University as a poor anticancer agent, was very effective in slowing the production of HIV. This compound is known as d4T or stavudine. Bristol-Myers Squibb developed the drug under the trade name Zerit and brought it to market in 1994.

Yung-Chi (Tommy) Cheng, Ph.D., the Henry Bronson Professor of Pharmacology, has worked on a parallel course. While Drs. Prusoff and Lin found drugs that work against AIDS, Dr. Cheng has sought ways to reduce their toxicity. Long-term usage of anti-retroviral AIDS drugs leads to a decline in the mitochondrial DNA of certain organs, impairing their ability to function properly. After a month or two of use, these agents can cause problems in nerves, the pancreas, muscles and the liver. Dr. Cheng's laboratory team studies drugs that will be active against the virus but will have no toxicity to the mitochondrial DNA.

One such drug turned out to be 3TC, a compound with positive and negative forms that mirror one another. Originally synthesized by a Canadian researcher and identified as an antiviral agent, samples were sent to Dr. Cheng for study of the drug's toxicity. He found that 3TC's negative form reduced side effects when used in combination with AZT. The combination increases 3TC's efficiency at inhibiting an enzyme HIV uses to reproduce its genetic material. Dr. Cheng identified 3TC as an agent that would be less toxic to mitochondrial DNA than other retroviral drugs.

A new approach to combating AIDS may grow out of work led by John K. Rose, Ph.D., Professor of Pathology and Cell Biology. The agent he developed, based on a common virus found in cattle, has killed HIV-infected cells in culture. He also sees the possibility of developing an AIDS vaccine, using recombinant form of the virus as a vaccine vector. Researchers hope the vaccine will stimulate both parts of the immune system: antibodies to neutralize any free-floating HIV and specialized immune cells to kill any cells that HIV does manage to infect. Early results using a form of the engineered virus showed promise against SIV, the simian form of HIV, for use in animal trials. Dr. Rose is working together with scientists at Wyeth Pharmaceuticals in conducting further animal tests. If it is proven safe and effective in animals, human trials could follow.

These are only a few examples of the life-changing discoveries resulting from Yale's scientific endeavors. Currently, Yale's has licensed eight (8) novel therapeutic drugs being tested in thirteen (13) different clinical trials for such life-threatening diseases as various types of cancer, Hepatitis B and AIDS (see attachment 1: Yale Pharmaceutical Pipeline). The benefit to the public derived from these and other inventions created through the research at Yale and other academic research institutions is incalculable.

THE BENEFITS OF COLLABORATIVE RESEARCH

The success of bringing these and countless university inventions to the marketplace has depended on rich collaborations among scientists within the university; collaborations among scientists at different universities; and collaborations among university and industry scientists. Collaboration among scientists in husbanding research dollars makes good sense with the cost and complexity of research today, especially with various institutions engaged in essentially the same technological

areas. Moreover, the evolution of science has made interdisciplinary research more and more common and, in fact essential, if solutions to complex problems are to be found. A very recent stunning example of this is the sequencing of the human genome.

Collaborative research among, private, public and non-profit entities is quantifiably important to the U.S. economy. In FY 2001 alone, based on data from 198 reporting institutions surveyed by AUTM:

- Sponsored research at academic institutions exceeded $31 billion.
- Over 4,000 new license and option agreements were executed with nearly 23,000 such agreements currently active.
- Nearly 360 new commercial products were brought to the market under license to a commercial partner. Since 1998, more than 1,500 new products have been introduced to the marketplace.
- 494 new companies were formed based on a license from an academic institution. Since 1980, over 3,800 such ventures have been created.

It is well known that industry depends heavily on collaborations with universities for basic research. In the pharmaceutical, biotech and hi-technology areas, America's universities are the engines of generating cutting-edge ideas that have kept this country's industries world leaders in new technology. Public funding of university research and the encouragement of collaborations among scientists at public, private and non-profit entities have been keystones of the United States' strength and leadership in these sectors. With the bulk of university research being supported through federal grants and contracts, to be prudent with the taxpayer's money, it again makes good policy sense to encourage collaboration among scientists for the public interest. These collaborations between scientists at separate universities and between industrial and university scientists often result in joint inventions. And actually, there has been an increase in the number of collaborations. Today Yale has over 100 inter-institutional agreements reflecting such collaborations. In these inter-institutional agreements, there is joint ownership of the results of the research by the collaborating scientists since most institutions operate under the provisions of the Bayh-Dole Act that give the institution the right to retain title to any invention made in whole or in part with federal funds. That is the applicable rule even where the institution is in a sub-contracting situation where the prime contractor is the recipient of federal funds. Thus, in inventions that result from collaborations, each party may hold ownership rights.

A THREAT TO COLLABORATIVE RESEARCH

In spite of the trend toward scientific collaboration and the economic and practical necessity for such collaborations, the recent decision of the U.S. Court of Appeals for the Federal Circuit in *OddzOn Products, Inc.* v. *Just Toys, Inc.*[1] threatens to discourage such collaborative activity. We are seriously concerned about the implications of this decision.

In *OddzOn*, the Federal Circuit interpreted subsection 103(c)of the Patent Act to hold that prior art under subsections 102(f) or (g) could be used to determine the obviousness of an invention in situations where:

(a) there was no common ownership or assignment of the invention and information being shared among the collaborators, and

(b) the information exchanged was not publicly known.

Prior to the *OddzOn* decision, it was uncertain whether information under 102(f) and (g) of the U.S. Patent Act (35 U.S.C.) that was shared among collaborators, but was not published or generally known, would qualify as prior art in determining whether an invention was obvious under section 103. Thus, there was some doubt as to whether courts would interpret 103(c) to distinguish collaborations involving one entity from those involving more than one entity.

The holding in *OddzOn*, while accurately interpreting the law, nonetheless is a wake-up call to the patent community that information under 102(f) or (g) could invalidate a patent in the circumstances of a collaborative research effort. The *OddzOn* decision creates a significant threat for the loss of intellectual property rights for inventors who engage in joint research and development projects with scientists not employed by the same company or institution. The implications of the *OddzOn* decision are significant. Researchers who enter into a well-defined and structured research collaboration, but who do not at that time transfer their rights (not only rights in future inventions, but also the background technology on which

[1] 122 F.3d 1396, 43 U.S. P.Q. 2d 1641 (Fed. Cir. 1997).

the collaboration is based) to a single entity can create obstacles to obtaining or enforcing a patent on an invention that arises out of the research collaboration. The information exchanged under the collaboration does not have to be publicly disclosed or commonly known. Instead, all that is required is that the collaborators exchange the information without first designating common ownership of the information or of any invention that may arise from the collaboration.

CONCLUSION

The *OddzOn* decision creates significant problems due to the very nature of collaborative research and development projects among universities, government labs, and industry. The unhindered flow of information among researchers within these collaborations is essential to the conduct of research and crucial to a successful outcome. Laws and policies that have the effect of impeding the flow of information among researchers will, for obvious reasons, have a stifling effect on the progress and success of such projects. We support efforts that will help to remedy undesirable impediments to collaborative research created by the *OddzOn* decision. This could readily result in more efficient development of products utilizing tax supported research results, and an increase in the transfer of technology for the public good.

Mr. Chairman, thank you again for your time and attention. If there are any questions, I will be pleased to answer them.

Attachment 1: YALE PHARMACEUTICAL PIPELINE

AGENT	LICENSEE	INDICATION		PATENT STAGE	EXPIRATION
Zerit®	Bristol-Myers Squibb	HIV / AIDS	Marketed	June 2008	
Coviracil®	Triangle Pharmaceuticals	Hepatitis B	Phase III	January 2010	
Pexelizumab™	Alexion Pharmaceuticals	Cardiopulmonary Bypass	Phase III	Pending	
Troxatyl®	Shire Pharmaceuticals	Acute Myelogenous Leukemia	Phase II	April 2017	
Troxatyl®	Shire Pharmaceuticals April 2017	Solid Tumors (pancreatic cancer)		Phase II	
Triapine™	Vion	Pharmaceuticals	Leukemia	Phase II	
January 2011					
Triapine™	Vion Pharmaceuticals	Metastatic Breast Cancer	Phase II	January 2011	
Clevudine™	Triangle Pharmaceuticals	Hepatitis B	Phase II	December 2013	
Elvucitabine™	Achillion Pharmaceuticals	Hepatitis B	Phase II	May 2014	
Elvucitabine™	Achillion Pharmaceuticals	HIV / AIDS	Phase II	May 2014	
TAPET™	Vion	Pharmaceuticals	Anticancer	Phase I	March
2013					
TAPET-CD	Vion	Pharmaceuticals	Anticancer	Phase I	March
2013					
VNP40101M	Vion	Pharmaceuticals	Anticancer (Solid Tumors)		Phase
I	March 2010				
VNP40101M	Vion	Pharmaceuticals	Anticancer (Leukemia)		Phase
I	March 2010				
loddU	Achillion Pharmaceuticals	Epstein-Barre Virus	Pre-clinical	Pending	
ACH0630	Achillion Pharmaceuticals	Hepatitis B and C	Pre-clinical	Pending	
VSV Vaccine	Wyeth Pharmaceuticals	HIV / AIDS	Pre-clinical	Pending	

Mr. SMITH. Mr. Steffe?

STATEMENT OF ERIC STEFFE, STERNE, KESSLER, GOLDSTEIN AND FOX, WASHINGTON, DC

Mr. STEFFE. Thank you, Mr. Chairman, for the opportunity to share my views here today. I would like to discuss from a practical perspective what happens for small or mid-sized biotech companies.

My law firm represents a very large number of small to mid-sized biotech companies and their operating budgets are anywhere between $3 to $5 million a year to $50 million a year. Most of them are attempting to develop products on their own, therapeutics, monoclonal antibody therapeutics, for example, in one instance, and to do that, to get FDA approval, it can cost anywhere between $150 to $500 million to go through the FDA approval process. So clearly, most, if not all, small to mid-sized biotech companies simply cannot afford to go all the way through the clinical trials process without forming a collaboration.

So what they do is they form secrecy agreements with interested other companies. They sometimes form secrecy agreements with universities. They exchange ideas, and based on this exchange of ideas, they make a decision as to whether they want to collaborate. If they go forward, they like the exchange of ideas, they like each other, they will go forward and they will form a collaboration.

As has already been pointed out, the concern of the current state of the law is that this exchange of ideas, if they are at different institutions, can itself create a prior art event under the patent law against a future joint invention arising out of the collaboration. So this, I do believe, has a chilling effect. The current state of the law has a chilling effect on these type of communications between different companies.

But again, it is a necessity, so companies are still doing it. They are still obviously out there collaborating and they have all the patent lawyers telling them that you have this concern of joint inventions. If they are not commonly assigned at the time the joint invention is made, you are going to have potential patentability obstacles to the improvement inventions that arise out of the collaboration.

So what do they do in this instance? Well, they either contractually assign all the rights to one entity or they just take their chances. If they take their chances, then the inventions that arise out of the collaboration must be novel and non-obvious on the merits, we call it in patent law. If they decide not to take their chances, they will assign to one institution or form a joint venture or what have you, if it is deemed by some examiner at the Patent Office that the joint invention is an obvious variation of an idea one of them brought to the table at the initial start of the collaboration.

So I support in particular the proposed amendment to 103(c) because right now under 103(c), the way it currently stands is you have to make this decision prospectively, looking forward. You have to make the decision to commonly assign inventions at the outset of the collaboration, before the invention is made, to benefit from 103(c), the safe harbor that this provides.

Under the proposed legislation, you have an additional period of time, up until the patent application is filed, that is after the invention is made out of the collaboration. You have some more time to decide whether common ownership is needed to overcome obstacles to obtaining a patent for an invention arising out of the joint venture. So in this way, the proposed legislation provides flexibility, I think, to companies that can assess inventions that arise out of collaborations and make the determination whether joint ownership is needed, or common ownership is needed, excuse me. So for that reason, I fully support 103(c) because of the added flexibility it provides.

Concerning the proposed amendment to 102(f), as I said, the companies form secrecy agreements and then they decided whether they want to go forward with the collaboration. Under proposed 102(f), you would no longer be able to make an obviousness rejection under this subsection of the statute. This is a good thing where collaborations go forward, because now companies can freely exchange ideas without worrying about shooting themselves in the foot later.

The only concern, the only caveat I can see with the proposed amendment to 102(f) is if a collaboration does not take place. What if they share secret information but they don't go forward? There may be a temptation under the proposed legislation, I think, to make a minor modification of an idea you got from a first company and then seek a patent on it, and under the proposed legislation it is possible a court would hold that the patent law would not reject that type of minor modification that an unscrupulous company may have stolen, for a lack of a better word, from the first company. I think a minor change to 102(f) could take care of that problem, and so I don't see that as being something that should hold up the legislation at all.

Thank you for your time. I appreciate the opportunity to share my views.

Mr. SMITH. Thank you, Mr. Steffe.

[The prepared statement of Mr. Steffe follows:]

PREPARED STATEMENT OF ERIC K. STEFFE

I. INTRODUCTION

Thank you Chairman Smith, Ranking member Berman and distinguished members of the Subcommittee on Courts, the Internet, and Intellectual Property of the United States House of Representatives for giving me the opportunity to testify regarding the "Cooperative Research and Technology Enhancement (CREATE) Act of 2003."

I am a partner at Sterne, Kessler, Goldstein & Fox, P.L.L.C., a law firm in Washington D.C. specializing in intellectual property.[1] I have been practicing biotech patent law for over twelve years and have lectured and published extensively on intellectual property issues arising out of industry collaborations, research tools and exemptions from patent infringement. With colleagues, I first published in 1999 regarding the issue CREATE addresses.[2] I commend the Committee for taking up the important issue addressed by this Bill.

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[1] This testimony reflects the present thoughts of its author, Eric K. Steffe, Esq., and should not be attributed to Sterne, Kessler, Goldstein & Fox P.L.L.C. or any of its former, current, or future clients.

[2] "Biotech Collaborations and Maximizing Patent Protection: Two Hypotheticals," 27 AIPLA Quarterly Journal 149 (1999). A copy of this article is attached.

II. BACKGROUND

35 U.S.C. § 103(a) states in part that "[a] patent may not be obtained [even though the claimed invention may be novel] . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. . . ."[3] Thus, a claimed invention must not only be novel, but also be nonobvious to be patentable. Importantly, a combination of prior art references or prior art "events" can be used to formulate an obviousness rejection under § 103.

The content of the prior art on which a finding of obviousness may be based is defined by subsections of 35 U.S.C. § 102.[4] Presently, 35 U.S.C. § 103(c) exempts subject matter defined by §§ 102(e), (f) and/or (g) from being used as prior art under § 103(a) when certain conditions are met.

A. Interplay Between 35 U.S.C. §§ 102(f) and 103

Whether 35 U.S.C. § 102(f) is a prior art section for the purposes of 35 U.S.C. § 103, thereby making § 102(f) art available for obviousness determinations, has been the subject of much controversy. Under § 102(f) a person is not entitled to a patent if "he did not himself invent the subject matter sought to be patented."[5] Section 102(f) applies not only to public knowledge, but also to private communications, even those made under a secrecy agreement. This has traditionally been considered a derivation provision, the purpose of which is to prevent someone from obtaining a patent on that which was invented by someone else. According to case law, two elements are required for establishing derivation under § 102(f). First, "the named inventor in the patent [must have] acquired knowledge of the claimed invention from another."[6] Second, there must have been a prior conception of the invention, and the conception must have been communicated.[7]

If § 102(f) is a prior art section for an obviousness analysis, then communications of less than the complete invention can be relied on to reject or invalidate a claim to the invention, under certain circumstances. In other words, viewing § 102(f) as a prior art section means that the contents of a communication can be combined with "traditional" prior art disclosures (journal articles, patents, prior uses, etc.) to render a later claimed invention obvious under § 103.

The case law is in a state of disarray concerning whether a derivation under § 102(f) can be combined with other prior art as the basis for a conclusion that the claimed invention is obvious under § 103, and therefore unpatentable. For example, the Federal Circuit and the CCPA have made conflicting statements about this issue in dictum in *New England Braiding*[8] and *In re Bass*[9] and in a dissenting opinion in *Lamb-Weston, Inc.* v. *McCain Foods, Ltd.*[10]

Further confusion was created by *Gambro Lundia AB* v. *Baxter Healthcare Corp.*[11] In Gambro, referring to the dictum in New England Braiding, the lower court concluded that to invalidate Gambro's patent under § 102(f), "Baxter did not need to prove communication of the entire conception, but rather only so much of the invention 'as would have made it obvious to one of ordinary skill in the art.'"[12] However, the Federal Circuit held that, its dictum in New England Braiding notwithstanding, the lower court's holding was clearly erroneous and "applied the

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[3] 35 U.S.C. § 103(a)

[4] *See* In re Yale, 347 F.2d 995, 1000, 146 USPQ 400, 403 (CCPA 1965); *see also* Panduit Corp. v. *Dennison Mfg. Co., 810 F.2d 1561, 1568, 1 USPQ2d 1593, 1597 (Fed. Cir. 1987)("Before answering Graham's 'content' inquiry, it must be known whether a patent or publication is in the prior art under 35 U.S.C. § 102. . . .").*

[5] 35 U.S.C. § 102(f).

[6] *New England Braiding Co., Inc.* v. *A.W. Chesterton Co.,* 970 F.2d 878, 883, 23 U.S.P.Q.2d 1622, 1626 (Fed. Cir. 1992).

[7] *See McSherry* v. *Giannuzzi,* 227 U.S.P.Q. 868, 872 (Bd. Pat. App. & Int. 1985), *aff'd,* 790 F.2d 95 (Fed. Cir. 1986); *see also Price* v. *Symsek*, 988 F.2d 1187, 1190, 26 U.S.P.Q.2d 1031, 1033 (Fed. Cir. 1993).

[8] 970 F.2d at 883, 23 U.S.P.Q.2d at 1626 ("To invalidate a patent for derivation of invention, a party must demonstrate that the named inventor in the patent acquired knowledge of the claimed invention from another, or at least so much of the claimed invention as would have made it obvious to one of ordinary skill in the art.")

[9] 474 F.2d 1276, 1290, 177 U.S.P.Q. 178, 189 (C.C.P.A. 1973) (§ 102(f) has "no relation to § 103 and no relevancy to what is "prior art" under § 103".).

[10] 78 F.3d 540, 548–49, 37 U.S.P.Q.2d 1856, 1863 (Fed. Cir. 1996)("Derived knowledge can indeed be invalidating [under § 102(f)], but this is not properly described as "prior art", which is defined as actual or presumed public knowledge.")(dissenting opinion).

[11] 110 F.3d 1573, 42 U.S.P.Q.2d 1378 (Fed. Cir. 1997).

[12] *Id.* at 1577, 42 U.S.P.Q.2d at 1382.

wrong legal standard" because it "introduces incorrectly an obviousness analysis into the test for derivation."[13]

The panel in Gambro, which was decided in April of 1997, included Chief Judge Archer and Circuit Judges Rader and Lourie. Later, in August of 1997, a different panel of the Federal Circuit, Circuit Judges Michel, Lourie, and Rader, reached the opposite conclusion in OddzOn Products, Inc. v. *Just Toys, Inc.*[14]

Citing 35 U.S.C. § 103(c)[15], the *OddzOn* panel stated that

> [w]hile the statute [§ 103(c)] does not expressly state in so many words that § 102 (f) creates a type of prior art for purposes of § 103, nonetheless that conclusion is inescapable; the language that states that § 102(f) subject matter is not prior art under limited circumstances clearly implies that it is prior art otherwise. That is what Congress wrote into law in 1984 and that is the way we must read the statute.[16]

The Federal Circuit in *OddzOn* did not cite *Gambro*, which was decided four months earlier, even though *Gambro* enunciated a different legal standard for derivation. According to the Federal Circuit in *Newell Co., Inc.* v. *Kenney Manufacturing Co.*,[17] where there is a conflict in statements of Federal Circuit law, the earlier statement prevails unless or until it has been overruled *en banc.*[18] Thus, if the issue of whether § 102(f) is a prior art section is again before the Federal Circuit, it would appear that a subsequent panel (if it followed *Newell*) would presumably be forced to hold in the negative and follow the enablement standard as enunciated by the panel in *Gambro*. In my view, absent legislation, an en banc decision will be necessary to fully resolve this issue.

B. Interplay Between 35 U.S.C. §§ 102(e), (g) and 103

In contrast to § 102(f), it is well settled that subject matter defined by §§ 102(e) or 102(g) is available as prior art in an obviousness analysis, subject to the limitations in § 103(c).

Under § 102(e), the disclosure of a U.S. patent application is prior art to subject matter invented by others after its U.S. filing date. However, such an application only becomes eligible for use as prior art upon publication of the application under 35 U.S.C. § 122(b), or upon maturation into a patent.[19]

Under § 102(g), a person is not entitled to a patent if "before [the patent applicant's] invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it."[20]

C. The § 103(c) Exemption

In 1984, Congress amended § 103 to disqualify events that fall exclusively within §§ 102(f) or (g) from use as prior art under § 103, if specific conditions are met. This amendment provided in pertinent part:

> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment with the same person.[21]

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[13] *See id.*

[14] 122 F.3d 1396, 43 U.S.P.Q.2d 1641 (Fed. Cir. 1997).

[15] A the time OddzOn was written, § 103(c) provided:

> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment with the same person.

Pub. L. No. 98–622, § 103, 98 Stat. 3384 (codified as amended at 35 U.S.C. § 103(c) (1984)).

[16] 122 F.3d at 1403, 43 U.S.P.Q.2d at 1646.

[17] 864 F.2d 757, 9 U.S.P.Q.2d 1417 (Fed. Cir. 1988).

[18] *See id.* at 765, 9 U.S.P.Q.2d at 1423 (stating that subsequent panel opinions may elaborate and refine and thus advance the evolution of judge made law, but they cannot change the law as established in prior rulings)(citing *U.M.C. Elec. Co.* v. *U.S.*, 816 F.2d 647, 652 n.6, 2 U.S.P.Q.2d 1465, 1468 n.7 (Fed. Cir. 1987)).

[19] 35 U.S.C. § 102(e)(1) and (2).

[20] 35 U.S.C. § 102(g)(2).

[21] Pub. L. No. 98–622, § 103, 98 Stat. 3384 (codified as amended at 35 U.S.C. § 103).

This amendment was reportedly in direct response to the decision in In re Bass,[22] which arguably created a disincentive to file patents early and discouraged communication between co-workers.[23] In support of the amendment, commentators argued that "[s]uch encouragement of ignorance defeats a fundamental principle of corporate research—the free exchange of ideas between corporate employees. Moreover, it runs counter to both the policy and the spirit of the patent laws because it discourages both invention and the prompt disclosure of new inventions."[24] Thus, recognizing the value of team research within corporations, businesses, and universities, Congress amended § 103 to eliminate these obstacles to team research.

In 1999, Congress again amended § 103 by passing the American Inventor's Protection Act ("AIPA"). This amendment enlarged the section 103(c) exemption to include section 102(e). Section 103(c) now provides that

> subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.[25]

Thus, the 1984 and 1999 amendments to § 103 disqualify "subject matter developed by another person" if it meets the following criteria:

1) it falls only within the definitions of sections 102(e), (f) and/or (g); and
2) the subject matter of the prior art and of the claimed invention were:
   a) commonly owned,[26]
   b) "at the time the [second] invention was made."

III. SOME OF THE ISSUES UNADDRESSED BY CURRENT § 103(C)

The benefits of having the earliest possible filing date for a patent application encourages filing the application as soon as possible after an initial discovery is made. However, due to the basic nature of biotech and pharmaceutical research, an initial discovery is often less commercially important than later discovered improvements. If the inventors of the later discovered improvements are not all under obligation to assign to the same entity, for example, if they are not employed by the same company, the situation is especially complex.

For example, assume that individuals α and β, employed at Company A, discover that a novel antigen, Antigen A, provides a low level of immunity in mice against a pathogen. Company A files a patent application naming α and β as co-inventors and claims Antigen A and its use as a vaccine against the pathogen. α and β then approach γ, who is employed by Company B, and who specializes in adjuvants. Based on her expertise, γ selects a number of adjuvants for testing. One adjuvant, Adjuvant X, is shown to reproducibly boost the immune response to Antigen A to the extent that nearly all immunized mice are protected from pathogenic challenge. Company A files a second application a year after the filing date of the first application claiming Antigen A/Adjuvant X and its use as a vaccine. Company A plans to market the improvement Antigen A/Adjuvant X as a vaccine for humans. The initial discovery claimed in the first application (the Antigen A compound) would be assigned to Company A. However, since γ is employed at Company B, the improvement (the Antigen A/Adjuvant X composition) would be assigned to both Company A and Company B.[27] Thus, not only would there be a potential obviousness rejection

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[22] In Bass the CCPA affirmed a rejection of claims in a pending application as obvious over an earlier invention by a different, although overlapping, set of inventors, that qualified as prior art under § 102(g). 474 F.2d at 1291, 177 U.S.P.Q. at 189.

[23] *See Section by Section Analysis: Patent Law Amendments of 1984,* 98th Cong., 130 CONG. REC. H 10525 (1984), reprinted in, 1984 U.S.C.C.A.N. 5827, 5833.

[24] *Patent Law Improvements Act: Hearing on S. 1535 and S. 1841 Before the Subcommittee on Patents, Copyrights, and Trademarks of the Senate Committee on the Judiciary,* 98th Cong., 157 (1984)(prepared statement of John E. Maurer).

[25] 35 U.S.C. § 103(c).

[26] When the PTO implemented § 103(c) by amending 37 C.F.R. § 1.104, it explained that common ownership by the same "person" or "organization" "would include circumstances where the ownership resided in more than one person and/or organization as long as the applications are owned jointly by the same owners. 50 Fed. Reg. 9368, 9373 (1985)(codified at 37 C.F.R. § pt. 1). In other words, for the § 103(c) exception to apply, there must be an identical "ownership entity" between the subject matter which would otherwise qualify as prior art under §§ 102(f) or (g) and the subsequent invention claimed in the later filed patent application.

[27] In the eyes of the PTO, Company is a different "ownership entity" than the joint entity of Company A-Company B. Final Rules for Miscellaneous Patent Provisions, 50 Fed. Reg. 9368, 9373 (1985)(codified at 37 C.F.R. § pt. 1).

under § 102(e)/§ 103 against a claim to the improvement in the second application if the first application were to be published or to issue as a patent, there would also potentially be an obviousness rejection under § 102(g)/§ 103 based on the prior reduction to practice of Antigen A by α and β. Further, if communications between co-inventors during the development of an invention can constitute prior art, there would potentially also be an obviousness rejection under § 102(f)/§ 103 based on α and β's communication of Antigen A to γ. This would arise because the second inventive entity, α, β and γ could be said to have derived the initial discovery, Antigen A, from the first inventive entity, α and β, rendering the improvement obvious if combined with other prior art subject matter.

Thus, these patentability issues must be considered in advance of collaborations between separate institutions. In the hypothetical, to fall within the exemption of § 103(c), Company A and Company B should have considered an agreement whereby Company B assigned or promises to assign its rights to all inventions arising out of the collaboration to Company A, or vice versa. This would have invoked § 103(c) of the statute by causing, at the time the improvement was made, the improvement and the initial discovery to be "owned by the same person or subject to an obligation of assignment to the same person."[28]

However, from a business standpoint, agreeing to assign all inventions arising out of the collaboration to Company A may be unacceptable to Company B. This is because each joint owner is an owner of an undivided one-half interest in the patent[29] and is said to be at the mercy of the other joint owners.[30,31]

Additionally, all co-owners must join in a patent infringement suit. Further, a "primary interest" of a co-owner is "the interest . . . in being able to license third parties under his or her patent without harassing suits by other co-owners."[32] Thus, clear advantages flow from being a joint owner of a patent, which may make Company B reluctant to enter into an agreement assigning its rights to inventions arising out of the collaboration to Company A.[33]

Moreover, under the Bayh-Dole Act, an institution that receives research funds from the government is severely restricted in its ability to assign rights for an invention developed using those funds. The Bayh-Dole Act established a presumption that contractors (i.e., a university or other non-profit institution that has entered into a funding agreement with a federal agency) will acquire title to patents directed to inventions arising out of federally funded research. If it is a nonprofit institution, the contractor cannot assign its rights in the invention in the United States to a third party without the approval of the federal agency. Thus, if one or both collaborating institutions is subject to this Act, that institution must first obtain approval from the federal agency before assigning any rights in the initial invention or the improvement invention. This may be difficult to obtain where it is not yet known whether the collaboration will lead to a significant invention.

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[28] 35 U.S.C. § 103(c).

[29] *Drake* v. *Hall,* 220 F. 905, 906 (7th Cir. 1915).

[30] *See* 5 E. LIPSCOMB'S WALKER ON PATENTS § 19:39 at 464–65 ("The tenant in common may make, use and sell specimens of the patented invention to any extent, and may license others to do so, and neither the tenant nor the tenant's licensees can be enjoined from a continuance in so doing. Nor can any recovery of profits or damages be had against such licensee at the suit of any co-tenant of any such licensor. And no recovery of profits or damages can be had against one co-tenant who, without the consent of the others, has made, used or sold specimens of the patented thing.") (footnotes omitted). *See generally* Robert P. Merges and Lawrence A. Locke, *Co-Ownership of Patents: A Comparative and Economic View*, 72 J. PAT. & TRADEMARK OFF. SOC'Y 586 (June 1990).

[31] The incidents of joint ownership are codified in 35 U.S.C. § 262 as follows:

> In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States without the consent of and without accounting to the other owners

35 U.S.C. § 262.

[32] *Willingham* v. *Lawton,* 555 F.2d 1340, 1344, 194 U.S.P.Q. 249, 252 (6th Cir. 1977).

[33] Alternatively, Companies A and B could have agreed to assign Company A's initial discovery and all inventions arising out of the collaborative research to a joint venture, incorporated by Companies A and B for the purpose of the collaboration. (This was previously suggested in an article by Virginia C. Bennett and Sorojini J. Biswas in *Protecting the patentability of your collaborative research*, 15 NATURE BIOTECHNOLOGY 472, 473 (1997).) Another option would be for Company A to agree, prior to the start of the collaboration, to assign to Company B an undivided, one-half interest in any patent application directed to Company A's initial discovery, with the assignment conditioned upon the development of patentable improvements from the collaboration. However, the barrier to such agreements is quite high. For example, Company A may not be willing to share its rights in Antigen A with Company B for only the possibility of the development of valuable improvements from the collaboration.

Consequently, none of the ownership alternatives above completely abrogates the § 102(e),(f) or (g)/§ 103 prior art problem that plagues collaborations between entities, and discourages free communication between inventors. Because of the great unpredictability and the difficulty in the valuation of potential discoveries from the collaboration, it would be quite valuable to be able to delay the decision of whether to assign until after the improvement invention is produced by the collaboration.

IV. THE PROPOSED AMENDMENT TO § 103(C)

The proposed bill, the "Cooperative Research and Technology Enhancement (CREATE) Act of 2003" would amend 35 U.S.C. §§ 102(f) and 103(c). The proposed amendment to § 102(f) would insert after "patented" the language "except that subject matter under this subsection shall not be considered prior art or as evidence of obviousness under section 103 of this title." In addition, the proposed amendment to § 103(c) would replace the current language with the following:

> Subject matter developed by another person, which qualifies as prior art only under one or both of subsections (e) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time of the earliest filing date for which a benefit is sought under this title, owned by the same person or subject to an obligation of assignment to the same person.

I support this bill, CREATE, because it decreases the barrier to research collaborations between different institutions by narrowing the circumstances in which an initial discovery may qualify as prior art to later developed improvements. CREATE does this in two ways.

First, CREATE picks up where the 1984 amendment to 35 U.S.C. § 103(c) left off. The 1984 amendment encouraged the free exchange of ideas between researchers within a single institution by removing §§ 102(f) and (g) as prior art sections for an obviousness analysis under § 103. However, it left this barrier in place for collaborations between separate institutions, because communication between inventors at different institutions still qualifies as prior art, unless an agreement is made, prior to the development of improvement inventions, to commonly assign ownership. CREATE removes § 102(f) as a prior art section for an obviousness determination under § 103. If enacted, this amendment would encourage communication between inventors, even where they are at separate institutions. Thus, CREATE recognizes the reality of scientific research today wherein collaborations between separate institutions are commonplace.

Second, CREATE amends § 103(c) to provide greater flexibility for collaborating institutions. Currently 103(c) requires that common ownership be in place "at the time the [improvement] invention was made" to avoid § 102(e) or (g) prior art being used for an obvious analysis under § 103. In contrast, the proposed amendment to § 103(c) provides flexibility to collaborating institutions by allowing them to delay the decision to create common ownership until a patent application is filed for the improvement. This gives collaborators time after the improvement invention is made to decide whether common ownership is needed to avoid the use of an earlier invention as § 102(e) or (g) prior art for § 103.

This amendment may be particularly important to nonprofit institutions, such as universities, that are covered by the Bayh-Dole Act. Such institutions need permission from the federal agency that funds their research to assign their patent rights. By allowing such institutions to delay the decision of whether it will be necessary to assign rights until after an improvement invention is made (but before an application for this invention is filed), CREATE may make it easier for the institution to obtain this permission.

In fact, I would go even further than the proposed amendments and would not remove mention of § 102(f) from § 103(c), but would amend § 102(f) to read "[a] person shall be entitled to a patent unless . . . he did not himself invent the subject matter sought to be patented, except that subject matter communicated from a coinventor shall not be considered prior art under this subsection."

My proposal would address the following issues. First, there may be a concern that the proposed bill inadvertently protects a party who misappropriates the invention of another party, makes minor modifications, and files a patent application, because unpatentability for obviousness based on 102(f) prior would no longer be available. However, an inventor could attempt to protect herself from this kind of predatory behavior by going to the expense of filing a patent application before communicating her idea to another, thus creating § 102(g) prior art against a patent application filed by the unscrupulous copier.

The second issue is illustrated by the following example: inventor A invents compound X. He then collaborates with inventor B, who works at a different company, and together they invent a "genus" of compounds that includes compound X. That is, together they invent a generic chemical formula that includes compound X as well as other compounds. Under the proposed bill, the generic chemical formula theoretically could be found unpatentable under § 102(f), even though compound X was not disclosed to the public before the invention of the generic formula, because the generic chemical formula lacks novelty over compound X. While, hopefully a court would consider the entire collaboration as an act of invention , and would refuse to find the generic formula unpatentable over the earlier communication of compound X for public policy reasons, CREATE arguably leaves this an open question.

In sum, I believe my proposal more surgically addresses the drawbacks of the current § 103(c) and mitigates unintended consequences.

ATTACHMENT

BIOTECH COLLABORATIONS AND MAXIMIZING PATENT PROTECTION: TWO HYPOTHETICALS*

ERIC K. STEFFE, HEIDI L. KRAUS AND ROBERT C. MILLONIG**
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.***

I. INTRODUCTION

The benefit of having an earlier filing date than the competition usually warrants filing a patent application soon after an initial discovery is made. However, due to the basic nature of Biotech research, an initial discovery is often less important commercially than later discovered improvements. When developing strategies to maximize patent protection, the interplay of patent issues for inventions resulting from the initial discovery and for inventions resulting from the improvement must be considered.

For example, if the first patent application, directed to the initial discovery, and the second patent application, directed to the improvement, do not name identical inventors, the first application may become available as prior art against the second application under certain circumstances. If not all inventors are employed by the same company the situation becomes more complex. If the initial discovery and the improvement are not commonly assigned, it is possible that the initial discovery may qualify as prior art against the improvement even if the initial discovery is never published and is never the subject of a patent application.

These considerations are discussed below together with recommendations for increasing the likelihood of obtaining patent protection for both the initial discovery and the improvement. The first hypothetical involves the situation where the original research team collaborates with additional researchers at the same company. In the second hypothetical, the collaboration involves researchers at different institutions.

II. COLLABORATIONS WITHIN A COMPANY

Assume that individuals α and β, employed at Company, discover that a novel antigen, Antigen A, provides a low level of immunity in mice against a pathogen. Company files a patent application naming α and β as co-inventors and claims Antigen A and its use as a vaccine against the pathogen. α and β then approach γ, also employed by Company, who specializes in adjuvants. Based on her expertise, γ selects a number of adjuvants for testing. After 10 months of testing, one adjuvant, Adjuvant X, is shown to reproducibly boost the immune response to Antigen A to the extent that nearly all immunized mice are protected from pathogenic challenge. Company files a second application a year after the filing date of the first application claiming Antigen A/Adjuvant X and its use as a vaccine. Company plans to market the improvement Antigen A/Adjuvant X as a vaccine for humans. [1]

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[1] If it is assumed that Antigen A is novel and nonobvious at the time the first application is filed, then open-ended claims could possibly be obtained in the first application encompassing Antigen A alone and Antigen A together with any other compound. Thus, while the first application would possibly dominate the Antigen A/Adjuvant X composition generically, it would not have support to specifically claim the Antigen A/Adjuvant X composition unless Adjuvant X was described in the as-filed specification. *See, e.g.*, University of California v. *Eli Lilly and Co., 119*

Continued

A first issue that must be considered is the inventorship of the second patent application. If the selection of Adjuvant X would have been obvious to one of ordinary skill in the art at the time the improvement was made, perhaps it could be argued that γ is not an inventor of the second patent application since γ contributed nothing novel and nonobvious to the invention. However, both Federal Circuit precedent and practical considerations suggest that inventorship determinations cannot be based solely on this type of an analysis. First, in *Burroughs Welcome Co.* v. *Barr Laboratories Inc.*[2] the Federal Circuit considered whether a United States Patent and Trademark Office (PTO) determination that certain claims were obvious over other prior art claims was relevant to a determination of whether the inventors of the two sets of claims were the same.[3] In this case, the obvious claims were directed to a method of increasing the number of T lymphocytes with AZT. The prior art claims were directed to a method of treating AIDS with AZT. In holding that the obviousness determination was not controlling, the court concluded, "[f]or conception, we look not to whether one skilled in the art could have thought of the invention, but whether the alleged inventors had in their minds the required definite and permanent idea."[4] Second, nonobviousness of an invention can be established long after a patent issues upon consideration of the so-called "secondary factors" of patentability. Thus, if inventorship were determined based on an obviousness analysis, inventorship would theoretically never be settled during the life of a patent.[5]

For the purpose of this hypothetical, we will assume that neither α nor β conceived of Adjuvant X. Therefore, regardless of whether the incorporation of Adjuvant X would have been obvious in light of the initial discovery, the holding in *Burroughs Welcome* suggests that γ should be named as an inventor of the second patent application.

When it issues as a patent, the disclosure of the first application becomes prior art under 35 U.S.C. § 102(e)[6] as of the date it was filed at the PTO. Since the invention claimed in the second application was invented "by another,"[7] the improvement may be held to be obvious over the disclosure of the first application by the PTO or a court even though there is common ownership.[8] Thus, before permitting the first application to issue, Company's patent attorney should weigh the probable strength of an obviousness rejection based on the first application against a claim specifically directed to the improvement. If there is a reasonable likelihood that such an obviousness rejection would be difficult to overcome, Company should consider incorporating the text of both applications into a continuation-in-part (CIP) applica-

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F.3d 1559, 1569, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997), In re Vaeck, 947 F.2d 488, 495–96, 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991). Hence, the second application is necessary to prosecute claims specifically directed to the commercial embodiment.

[2] 40 F.3d 1223, 32 U.S.P.Q.2d 1915 (Fed. Cir. 1994), *cert. denied*, 516 U.S. 1070–1071, 516 S. Ct. 771 (1996).

[3] *See id.* at 1231–32, 32 U.S.P.Q.2d at 1923.

[4] *Id.* at 1232, 32 U.S.P.Q.2d at 1923.

[5] This is not to say that an obviousness analysis has no role to play in making inventorship determinations. Inventorship is determined by identifying those individuals who contributed to a legally adequate conception. In determining whether a conception, containing all elements of a claimed invention, is sufficiently definite, the settled test is whether "the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." *Id.* at 1228, 32 U.S.P.Q.2d at 1919. This determination may include certain elements of an obviousness analysis. *See infra* note 45. However, it appears that reference to ordinary skill cannot substitute for a missing element of the claimed invention that was not part of the conception.

[6] Under section 102(e), "[a] person shall be entitled to a patent unless . . . the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent. . . ." 35 U.S.C. § 102(e).

[7] The inventors of Antigen A (i.e, α and β) would be a different inventive entity than the inventors of Antigen A/Adjuvant X (i.e., α, β and γ), even though α and β overlap both groups. *See In re* Land, 368 F.2d 866, 881, 151 U.S.P.Q. 621, 634 (C.C.P.A. 1966); *see also, Section by Section Analysis: Patent Law Amendments of 1984*, 98th Cong., 130 Cong. Rec. H 10525 (1984), *reprinted in*, 1984 U.S.C.C.A.N. 5827, 5834; *cf. In re Kaplan*, 789 F.2d 1574, 1575, 229 U.S.P.Q. 678, 679 (Fed. Cir. 1986) ("It is a given . . . that a sole inventor and joint inventors including the sole inventor are separate 'legal entities,' a legal proposition from which certain legal consequences flow 'such as who must apply for patent.'") (citation omitted).

[8] Prior art under 35 U.S.C. § 102(e) can be used by the PTO to reject claims as being obvious under 35 U.S.C. § 103. Obviousness rejections can combine the disclosures of more than one prior art document. Thus, the text of the first application, which discloses Antigen A, and one or more other references, which disclose Antigen X, could be relied on to reject the improvement as being *prima facie* obvious if the examiner could demonstrate that one of ordinary skill would have been motivated to combine the references to arrive at the claimed invention. To overcome it on the merits, such a *prima facie* rejection could be "attacked" with an argument that there would have been no motivation to combine the references or "rebutted" with extrinsic evidence, such as evidence of unexpected results.

tion[9] that claims both the initial discovery and the improvement and names α, β and γ as co-inventors. After the CIP has been filed claiming priority under 35 U.S.C. § 120[10] to the first and second applications, the first and second applications should be abandoned. Hence, the initial discovery and the improvement would be prosecuted out of the CIP and the potential § 102(e) prior art problem never materializes because no patent "by another" could issue due to the abandonment of the first application.

As a caveat, in the above hypothetical, assume that the first application was filed one year prior to the filing date of the second application. These filing dates would not necessarily have affected the patent term if the filings occurred prior to June 8, 1995, as such patent terms end 17 years from the date of issuance. However, on June 8, 1995, the General Agreement on Tariffs and Trade Act (GATT Act) took effect, which implemented Article 33 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). Under the GATT Act, the patent term still begins upon the date a patent issues, but it now expires 20 years from the earliest U.S. filing date.[11] Thus, by filing a CIP and claiming priority to both the first and second applications, the U.S. filing date for the purpose of calculating the patent term becomes the filing date of the first application, which would cause a one year loss of patent term for claims specifically directed to the improvement. If Antigen A/Adjuvant X turns out to be a multimillion dollar a year therapy, a one year loss in patent term could be worth millions of dollars.[12] On the other hand, this monetary loss is perhaps mitigated by the following consideration: by combining the first and second applications into a CIP, Company is able to obtain claims specifically directed to the improvement and also generic claims that would potentially dominate Antigen A in combination with any other compound, which makes it difficult for a competitor to invent around the commercial embodiment simply by using a different adjuvant.

The above strategy for overcoming Company's own § 102(e) prior art was made possible by the enactment of the Patent Law Amendments Act of 1984,[13] which amended the first paragraph of 35 U.S.C. § 116 to read:

> When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.[14]

Thus, in the above hypothetical, it is possible to prosecute the initial discovery and the improvement in the same CIP application even though inventor γ did not make a conceptual contribution to every claim of the CIP.[15]

Avoiding a § 102(e) rejection by combining two commonly owned applications into one CIP was specifically approved by the PTO in published explanatory comments

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[9] "A CIP is an application filed during the lifetime of an earlier [nonprovisional] application by the same applicant, repeating some substantial portion or all of the earlier [nonprovisional] application and *adding matter not disclosed* in the said earlier [nonprovisional] application." *In re* Klein, 1930 C.D. 2, 393 O.G. 519 (Comm'r Pat. 1930).

[10] Section 120 of the Patent Act states the following:

> An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States . . . which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

35 U.S.C. § 120.

[11] *See* 35 U.S.C. § 154(a)(2).

[12] An alternative would be to simply not claim priority to the first application. This would result in the generic claims to Antigen A only being entitled to the second application's filing date, but would extend the patent term for both inventions further into the future. However, this strategy would risk the invalidity of the generic claims to Antigen A based on prior art published or otherwise available subsequent to the first filing date. Therefore, it would be rare that this risk would be justified.

[13] Pub. L. No. 98–622, § 104(a), 98 Stat. 3384, 3385 (1984) (codified as amended at 35 U.S.C. § 116).

[14] 35 U.S.C. § 116, para. 1.

[15] The third criterion in the first paragraph of amended 35 U.S.C. § 116 abrogated the "all-claims" rule that had been adopted by some courts requiring that each named inventor have contributed to each claim of the patent.

when it promulgated rules under amended § 116.[16] However, as a caveat, at least one commentator has urged caution before following this strategy in light of the traditional collaboration requirement of joint inventorship under certain circumstances.[17] Citing Donald Chisum,[18] other statutes and the legislative history of the Patent Amendments Act of 1984, this commentator concludes that "Congress's relaxation of the strict 'all claims' rule does not show an intent to abrogate the collaboration, or joint manner, requirement."[19] Indeed, retaining the collaboration requirement for joint inventorship would appear to be supported by Federal Circuit case law since 1984.[20]

Prior to 1984, at least in certain circuits, all the inventors named in an application were also inventors of every claim in the application. Thus, the named inventors must have collaborated on every claim of the application. Following the 1984 amendment, the inventors of a particular claim in an application can differ from the named inventors of the application.[21] While it is clear that the collaboration requirement survives the 1984 amendment of section 116, it is not clear whether compliance with the collaboration requirement is determined for the application as a whole or on a claim-by-claim basis.

If the collaboration requirement is determined for the application as a whole, there must be some minimal collaboration between all named inventors even if different inventors contributed to separate, perhaps patentably distinct, claims.[22] However, if compliance with the collaboration requirement is determined on a claim-by-claim basis, it would only be necessary that joint inventors of a particular claim collaborate, but not that all inventors named on the application collaborate.

In our hypothetical, the collaboration requirement would be satisfied under either the application as a whole or the claim-by-claim analysis. Under the application as a whole analysis, the issue would be whether all the named inventors of the application at least minimally collaborated with each other in some way. For example, in the above hypothetical, assume that claim 1 in the CIP is directed to the Antigen A compound and claim 2 is directed to the Antigen A/Adjuvant X composition. Because α, β, and γ all collaborated in the joint invention of claim 2, under the application as a whole analysis, the collaboration requirement is satisfied. Under the claim-by-claim analysis, one looks to the inventorship of each claim, including assessing compliance with the collaboration requirement separately for each claim. Once inventorship is determined for each claim, the inventors named on the application are merely the summation of the inventors named for each claim. In the hypothetical, since α and β collaborated during the conception of the invention defined by claim 1, and α, β, and γ collaborated during the conception of the invention defined by claim 2, the collaboration requirement would also be met under the claim-by-claim analysis.

However, this would change if our hypothetical is modified so that a claim 3 is added directed to Antigen B, which was solely and independently conceived by δ. If we assume that δ did not collaborate with α, β, or γ during the conception of Antigen B, the collaboration requirement would presumably not be satisfied based on the application as a whole analysis, but would be satisfied under a claim-by-claim approach.

A claim-by-claim approach appears to have been favored by the PTO when it promulgated 37 C.F.R. § 1.45(c),

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[16] *See* Final Rules For Miscellaneous Patent Provisions, 1053 O.G. 10 (1985).

[17] *See* W. Fritz Fasse, *The Muddy Metaphysics of Joint Inventorship: Cleaning Up After The 1984 Amendments to 35 U.S.C. § 116*, 5 HARV. J.L. & TECH. 153, 207–08 (1992).

[18] *See* 7 DONALD S. CHISUM, PATENTS § 2.02[2], at 2–13 (July 1998) ("There is no evidence that Congress intended to discard the fundamental requirement [when enacting the Patent Law Amendments Act of 1984] that there be some form of collaboration between the joint inventors in the development of the final invention.").

[19] *See* Fasse, *supra note* 17, at 179.

[20] *See* Kimberly-Clark Corp. v. *Procter & Gamble Distrib. Co., Inc., 973 F.2d 911, 917, 23 U.S.P.Q.2d 1921, 1926 (Fed. Cir. 1992) ("[T]here must be some element of joint behavior, such as collaboration or working under common direction. . . . Inventors cannot be totally independent of one another and be joint inventors.").*

[21] If claim 1 was invented by α and β and claim 2 was invented by α, β, and γ, the inventorship named on the application would be α, β, and γ, which differs from the inventors of claim 1 (α and β).

[22] Under current P.T.O. practice it is possible for claims to patentably distinct inventions to be included in the same patent application if the examination of these claims would not constitute an undue burden on the examiner. *See, e.g.,* MANUAL OF PATENT EXAMINING PROCEDURE § 803, at 800–3 (7th Ed.1998) (For a restriction requirement to be proper, the inventions must be independent or distinct as claimed, *and* examining the inventions together must place a serious burden on the examiner).

> [i]f multiple inventors are named in a nonprovisional application, each named inventor must have made a contribution, *individually* or jointly, to the subject matter of at least one claim of the application and the application will be considered to be a joint application under 35 U.S.C. 116.[23]

This suggests that the claim-by-claim approach to the collaboration requirement is proper absent evidence to the contrary.

In summary, a viable strategy for Company to overcome a potential obviousness rejection based on prior art under § 102(e) is to abandon the first and second applications after filing a CIP and prosecuting both the initial discovery and the improvement in one application. However, Company should keep in mind that naming multiple inventors in one application may only be proper if there was at least some minimum element of collaboration between each of the named individuals even though they may not have contributed conceptually to every claim.

III. COLLABORATIONS WITH AN INDUSTRIAL PARTNER

In the above hypothetical, assume that α and β are employed by Company, but γ is employed by Industrial Partner (IP).[24] Thus, the initial discovery claimed in the first application (the Antigen A compound) would be assigned to Company. However, since γ is employed at IP, the improvement (the Antigen A/Adjuvant X composition) would be assigned to both Company and IP.[25] Thus, not only would there be a potential obviousness rejection under §§ 102(e)/103 against a claim to the improvement in the second application if the first application were to issue as a patent, there would also potentially be an obviousness rejection under §§ 102(g)/103 based on the prior reduction to practice of Antigen A by α and β. Further, if communications between co-inventors during the development of an invention can constitute prior art, there would potentially also be an obviousness rejection under §§ 102(f)/103 based on α and β's communication of Antigen A to γ. Moreover, the obviousness rejections based on § 102(f) and § 102(g) could not be overcome by combining the first two applications into a CIP.[26] Sections 102(f) and 102(g) of the patent statute and their applicability to the present hypothetical are discussed in more detail below.

A. Are Sections 102(f) and 102(g) Prior Art Sections?

Whether § 102(f) is indeed a prior art section,[27] making 102(f) art available in obviousness determinations, has been the subject of much controversy. The literal

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[23] 37 C.F.R. § 1.45(c) (1997) (emphasis added).

[24] Due to the obstacles associated with identifying and developing a potential drug, alliances in Biotechnology have become a necessity for many companies whose platform is based on a vast set of data which provides a seemingly endless number of potential targets or compounds that need screening. According to Ernst & Young, LLP, from 1995 to 1997 the following Biotech alliances were formed by technology: 10 in Carbohydrates/Cell Adhesion; 48 in Gene/Cell Therapy; 44 in Genomics; 56 in Molecular Diversity; 27 in monoclonal antibodies; 12 in Antisense; 5 in photodynamic therapy; 48 in rDNA; 29 in signal transduction; and 8 in Transgenics. *See* ERNST & YOUNG, LLP, BIOTECH 97: ALIGNMENT, THE ELEVENTH INDUSTRY ANNUAL REPORT, at 26 (1996). The following are examples of a few of the specific alliances formed in 1997, as reported by Ernst & Young, LLP: Hybridon and G.D. Searle & Co, entered into an agreement worth nearly $200 million to develop antisense drugs for immune system regulation. Searle also announced a deal with CoCensys for $80 million to develop insomnia drugs. Pfizer entered into an agreement with Megabios for $50 million for developing gene therapy treatments of lung cancer; Myriad Genetics and Bayer Corp. signed a $71 million partnership to search for genes related to osteoporosis, obesity and asthma; and Ophidian and Eli Lilly entered into a deal potentially worth more than $12 million to develop therapeutics for gastrointestinal infections. *See id.* at 29.

[25] In the eyes of the PTO, Company is a different "ownership entity" than the joint entity of Company-IP Final Rules for Miscellaneous Patent Provisions, 50 Fed. Reg. 9368, 9373 (1985) (codified at 37 C.F.R. § pt. 1). This issue is discussed in greater detail below at pages 17–18.

[26] When joint inventors are named in an application, the PTO presumes that all claims are assigned to single "ownership entity". *See* MANUAL OF PATENT EXAMINING PROCEDURE § 706.02 (m), ¶ 7.20.02 (7th Ed.1998) ("In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).").

[27] If § 102(f) is a prior art section then, if certain circumstances are met, communications of less than the complete invention as claimed can be relied on to reject or invalidate a claim. In other words, viewing § 102(f) as a prior art section means that the contents of a communication

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wording of § 102(f) provides that a person shall be entitled to a patent unless "he did not himself invent the subject matter sought to be patented."[28] This has traditionally been considered a derivation provision, the purpose of which is to prevent someone from obtaining a patent on that which was invented by someone else. It does not only pertain to public knowledge, but also applies to private communications, even those made under a secrecy agreement.

According to case law, two elements are required for establishing derivation under § 102(f). First, "the named inventor in the patent [must have] acquired knowledge of the claimed invention from another."[29] Second, there must have been a prior conception of the invention, and the conception must have been communicated.[30] In patent law, an invention is deemed to have been conceived when there is a "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention."[31] Thus, a prior reduction to practice of the invention by another is not required to establish derivation under § 102(f), provided that there was a prior conception and a communication.

However, the case law has been in a state of disarray concerning whether a derivation under § 102(f) can be combined with other prior art in an obviousness rejection under § 103. For example, the Federal Circuit stated in dictum in *New England Braiding*[32] that "[t]o invalidate a patent for derivation of invention, a party must demonstrate that the named inventor in the patent acquired knowledge of the claimed invention from another, or *at least so much of the claimed invention as would have made it obvious to one of ordinary skill in the art*."[33] This dictum in *New England Braiding* conflicts with dictum in *In re Bass*[34] and also conflicts with the dissenting opinion in *Lamb-Weston, Inc.* v. *McCain Foods, Ltd.*[35]

Further confusion appears in *Gambro Lundia AB* v. *Baxter Healthcare Corp.*[36] In *Gambro*, while referring to the dictum in *New England Braiding*, the lower court concluded that to invalidate Gambro's patent, "Baxter did not need to prove communication of the entire conception, but rather only so much of the invention 'as would have made it obvious to one of ordinary skill in the art.'"[37] However, the Federal Circuit held that, its dictum in *New England Braiding* notwithstanding, the lower court's holding was clearly erroneous and "applied the wrong legal standard" because it "introduces incorrectly an obviousness analysis into the test for derivation."[38] According to the Federal Circuit, the proper standard for finding communication of a prior conception was enunciated by the Supreme Court over 125 years ago in *Agawam Woolen Co.* v. *Jordan*,[39] wherein the Court required a showing that the communication "*enabled* an ordinary mechanic, without the exercise of any ingenuity and special skill on his part, to construct and put the improvement in successful operation."[40] Further, the Federal Circuit pointed out that this *enablement* standard for finding communication of a prior conception had been consistently applied by the Federal Circuit's predecessor, the CCPA.[41]

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can be combined with "traditional" prior art disclosures (journal articles, patents, prior uses, etc.) to render a later claimed invention obvious under § 103.

[28] 35 U.S.C. § 102(f).

[29] *New England Braiding Co., Inc.* v. *A.W. Chesterton Co.,* 970 F.2d 878, 883, 23 U.S.P.Q.2d 1622, 1626 (Fed. Cir. 1992).

[30] *See McSherry* v. *Giannuzzi,* 227 U.S.P.Q. 868, 872 (Bd. Pat. App. & Int. 1985), *aff'd,* 790 F.2d 95 (Fed. Cir. 1986); *see also Price* v. *Symsek*, 988 F.2d 1187, 1190, 26 U.S.P.Q.2d 1031, 1033 (Fed. Cir. 1993).

[31] *Hybritech, Inc.* v. *Monoclonal Antibodies, Inc.,* 802 F.2d 1367, 1376, 231 U.S.P.Q. 81, 87 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947, 107 S. Ct. 1606 (1987). However, conception of a chemical compound requires more than just a conception of biological activity. It requires the ability of an inventor to describe his or her invention with sufficient particularity to structurally distinguish the compound from other compounds. *See Fiers* v. *Revel, 984 F.2d 1164, 1169, 25 U.S.P.Q.2d 1601, 1605 (Fed. Cir. 1993).*

[32] 970 F.2d at 878, 23 U.S.P.Q.2d 1622.

[33] *Id.* at 883, 23 U.S.P.Q.2d at 1626 (emphasis added)

[34] 474 F.2d 1276, 1290, 177 U.S.P.Q. 178, 189 (C.C.P.A. 1973) (§ 102(f) has "no relation to § 103 and no relevancy to what is "prior art" under § 103".). This decision is discussed in greater detail below at page 15.

[35] 78 F.3d 540, 548–49, 37 U.S.P.Q.2d 1856, 1863 (Fed. Cir. 1996) ("Derived knowledge can indeed be invalidating [under § 102(f)], but this is not properly described as "prior art", which is defined as actual or presumed public knowledge.") (dissenting opinion).

[36] 110 F.3d 1573, 42 U.S.P.Q.2d 1378 (Fed. Cir. 1997).

[37] *Id.* at 1577, 42 U.S.P.Q.2d at 1382.

[38] *See id.*

[39] 74 U.S. (7 Wall.) 583 (1868).

[40] Gambro Lundia, 110 F.3d at 1577, 42 U.S.P.Q.2d at 1382 (quoting Agawam Woolen, 74 U.S. (7 Wall.) at 602–603).

[41] *See* Gambro Lundia, 110 F.3d at 1577, 42 U.S.P.Q.2d at 1382 ("Communication of a complete conception must be sufficient to *enable* one of ordinary skill in the art to construct and

The panel in *Gambro*, which was decided in April of 1997, included Circuit Judge Rader, Chief Judge Archer and Circuit Judge Lourie. Later, in August of 1997, a different panel of the Federal Circuit (Circuit Judges Michel, Lourie, and Rader) again turned the derivation standard on its head in *OddzOn Products, Inc.* v. *Just Toys, Inc.*[42] While citing § 103(c) of the patent statute,[43] the *OddzOn* panel stated that

> [w]hile the statute [§ 103(c)] does not expressly state in so many words that § 102 (f) creates a type of prior art for purposes of § 103, nonetheless that conclusion is inescapable; the language that states that § 102(f) subject matter is not prior art under limited circumstances clearly implies that it is prior art otherwise. That is what Congress wrote into law in 1984 and that is the way we must read the statute.[44]

Interestingly, the Federal Circuit in *OddzOn* did not cite *Gambro*, which was decided four months earlier, even though *Gambro* enunciated a different legal standard for derivation.[45] According to the Federal Circuit in *Newell Co., Inc.* v. *Kenney Manufacturing Co.*,[46] where there is a conflict in statements of Federal Circuit law, the earlier statement prevails unless or until it has been overruled *en banc*.[47] Thus, if the issue of whether § 102(f) is a prior art section is again before the Federal Circuit, it would appear that a subsequent panel (if it followed Newell) would presumably be forced to hold in the negative and follow the enablement standard as enunciated by the panel in *Gambro*. In our view, an *en banc* decision will be necessary to fully resolve this issue.

In contrast to § 102(f), the case law is rather well settled that art qualifying under § 102(g) is available as prior art in an obviousness analysis, subject to the limitations discussed in subsections B and C below. Under the first sentence of § 102(g), a person is not entitled to a patent if "before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it."[48] While § 102(g) is typically associated with interferences, it may also be a grounds for invalidity in other contexts such as a defense in patent infringement litigation and during *ex parte* prosecution.[49] In order to constitute prior art under § 102(g), the invention must have been reduced to practice in the United States and it cannot have been abandoned, suppressed or concealed. The reduction to practice can be an actual reduction to practice, by actually completing the inven-

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successfully operate the invention.") (emphasis added) (quoting *Hedgewick* v. *Akers*, 497 F.2d 905, 908, 182 U.S.P.Q. 167, 169 (C.C.P.A. 1974)); *see also DeGroff* v. *Roth*, 412 F.2d 1401, 1406, 162 U.S.P.Q. 361, 365 (C.C.P.A. 1969).

[42] 122 F.3d 1396, 43 U.S.P.Q.2d 1641 (Fed. Cir. 1997).

[43] In the Patent Law Amendments Act of 1984, Congress amended § 103 to disqualify events that fall exclusively within §§ 102(f) or (g) from use as prior art under § 103, if specific conditions are met. Pub. L. No. 98–622, § 103, 98 Stat. 3384 (codified as amended at 35 U.S.C. § 103). This amendment can now be found in subsection (c) of § 103, which provides:

> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment with the same person.

35 U.S.C. § 103(c).

[44] 122 F.3d at 1403–02, 43 U.S.P.Q.2d at 1646.

[45] However, as discussed in Chisum, "[i]t is not clear whether this standard [i.e, the enablement standard enunciated in *Agawam Woolen*] means enablement of a mechanic with presumed knowledge of all the prior art (as with Section 103) . . . or simply enablement of a mechanic with the ordinary level of skill (as with the disclosure standard of Section 112). . . . If it means the former, then. . . . Section 102(f) would itself contain an obviousness standard." 2 DONALD S. CHISUM, PATENTS § 5.03[3], at 5–177 n.59 (July 1998). Thus, depending on the scope given to the enablement standard in Gambro, it is possible that there may be some overlap between the *Gambro* and *OddzOn* legal standards for derivation when applied to a particular fact situation.

[46] 864 F.2d 757, 9 U.S.P.Q.2d 1417 (Fed. Cir. 1988).

[47] *See id.* at 765, 9 U.S.P.Q.2d 1423 (stating that subsequent panel opinions may elaborate and refine and thus advance the evolution of judge made law, but they cannot change the law as established in prior rulings) (citing U.M.C. Elec. Co. v. *U.S.*, 816 F.2d 647, 652 n.6, 2 U.S.P.Q.2d 1465, 1468 n.7 (Fed. Cir. 1987)).

[48] 35 U.S.C. § 102(g).

[49] *See Checkpoint Sys., Inc.* v. *United States Int'l Trade Comm'n,* 54 F.3d 756, 761, 35 U.S.P.Q.2d 1042, 1046 (Fed. Cir. 1995) (affirming an ITC decision that held patent claims invalid as anticipated by art qualifying as prior art only under section 102(g)).

tion, or a constructive reduction to practice, by filing a patent application that satisfies the requirements of 35 U.S.C. § 112, first paragraph.[50]

A reduction to practice (actual or constructive) does not constitute prior art under § 102(g) if the invention was abandoned, suppressed, or concealed.[51] In order to constitute an actual reduction to practice the invention must be reduced to a physical or tangible form.[52] With few exceptions, the invention must have been tested to confirm that it works for its intended purpose.[53] Moreover, § 102(g) does not contain a "personal knowledge requirement" or a "known to the art requirement."[54] Thus, provided that there has been no abandonment, suppression, or concealment, under § 102(g) the prior work of another can constitute secret prior art against the work of a second inventive entity even where the prior work was not publicly known in the art and second inventive entity had no knowledge of it.[55]

B. The § 103(c) Exception to 35 U.S.C. §§ 102(f) and 102(g) as Prior Art Sections.

35 U.S.C. § 103 states in part that "[a] patent may not be obtained [even though the claimed invention may be novel] . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. . . ." Thus, a claimed invention must not only be novel, but also nonobvious to be patentable. Importantly, a combination of prior art references or prior art "events" (e.g., a prior reduction to practice by another) can be used to formulate an obviousness rejection under § 103.

In *In re Bass*[56], the PTO rejected claims in a patent application naming Bass, Jenkins, and Harvat as co-inventors as being obvious over previously filed issued patents to Bass and Jenkins.[57] The PTO's rationale was that the claims in the later filed patent application were merely an obvious variation of what had been reduced to practice in the earlier filed issued patents and thus the patent application was properly rejected under § 103 by virtue of § 102(g). Importantly, one of the two earlier filed issued patents was ultimately deemed to be by "another" for purposes of the § 102(g) analysis even though there was an overlapping inventor.[58] In other words, the rejection was deemed to be applicable because the "inventive entity" of the earlier filed issued patents was not identical to the "inventive entity" of the later filed patent application. Also, the rejection was deemed appropriate even though the invention and the earlier reduction to practice occurred within the same company. The PTO's rejection was upheld by the Court of Customs and Patent Appeals (CCPA), which was the predecessor court of the Court of Appeals for the Federal Circuit (Federal Circuit).

In 1984, Congress amended § 103 to disqualify events that fall exclusively within §§ 102(f) or (g) from use as prior art under § 103, if specific conditions are met.[59]

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[50] *See In re Katz,* 687 F.2d 450, 454, 215 U.S.P.Q. 14, 17 (C.C.P.A. 1982) ("No possible barrier is created by § 102(g) unless another has either actually reduced the invention to practice or has constructively reduced it to practice by filing a patent application."); *see also Ex parte* Osmond, 191 U.S.P.Q. 340, 341 (P.T.O. Bd. App. 1976).

[51] If an application describing the invention is subsequently abandoned, the right to rely on a constructive reduction to practice is lost. With respect to an actual reduction to practice, "[t]he courts have consistently held that an invention, though completed, is deemed abandoned, suppressed, or concealed if within a reasonable time after completion, no steps are taken to make the invention publicly known. Thus, failure to file a patent application; to describe the invention in a publicly disseminated document; or to use the invention publicly have been held to constitute abandonment, suppression, or concealment." International Glass Co., Inc. v. *United States, 408 F.2d 395, 403, 159 U.S.P.Q. 434, 441 (Ct. Cl. 1968) (citations omitted); see also See E.I. du Pont de Nemours & Co.* v. *Phillips Petroleum Co.* 849 F.2d 1430, 1436 n.5, 7 U.S.P.Q.2d 1129,1134 n.5 (Fed. Cir.), *cert. denied*, 488 U.S. 986, 109 S. Ct. 542 (1988) ("[T]he filing of a United States patent application maintains the secrecy of work, but is a factor cutting against abandonment, suppression, or concealment.").

[52] *See Wetmore* v. *Quick,* 536 F.2d 937, 941, 190 U.S.P.Q. 223, 227 (C.C.P.A. 1976).

[53] *See Estee Lauder Inc.* v. *L'Oreal,* S.A., 129 F.3d 588, 593, 44 U.S.P.Q.2d 1610, 1614 (Fed. Cir. 1997) ("[A] reduction to practice does not occur until the inventor has determined that the invention will work for its intended purpose.").

[54] *See* E.I. du Pont de Nemours, 849 F.2d at 1437, 7 U.S.P.Q.2d at 1134–35.

[55] *See id.* (prior secret invention of Witt and Leatherman is relevant to validity of patent to Andersen and Stumatoff under 35 U.S.C. §§ 102(g)/103.)

[56] 474 F.2d 1276, 177 U.S.P.Q. 178.

[57] *See id.* at 1277, 177 U.S.P.Q. at 179.

[58] The disclosure in the second patent was excluded from consideration as prior art, since the disclosure in that patent and in the rejected claims were part of the same research and development program and were invented simultaneously.

[59] Pub. L. No. 98–622, § 103, 98 Stat. 3384 (codified as amended at 35 U.S.C. § 103).

This amendment can now be found in subsection (c) of § 103, which provides in pertinent part:

> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment with the same person.

13 U.S.C. § 103 (c).

This amendment was reportedly in direct response to the *Bass* decision, which arguably created a disincentive to file patents early and discouraged communication between co-workers.[60] In support of the amendment, commentators argued that "[s]uch encouragement of ignorance defeats a fundamental principle of corporate research—the free exchange of ideas between corporate employees. Moreover, it runs counter to both the policy and the spirit of the patent laws because it discourages both invention and the prompt disclosure of new inventions."[61] Thus, recognizing the value of team research within corporations, businesses, and universities, Congress amended § 103 to eliminate these obstacles to team research.

Interestingly, the enacted version of the 1984 amendment to § 103 is considerably different from the version first proposed by Representative Kastenmeir in the House of Representatives on November 18, 1983.[62] The original bill, entitled H.R. 4525, provided that "[p]rior art shall not include unpublished information which is developed by the applicant singly or jointly with others, or which is known to the applicant only by virtue of his or her employment."[63] Thus, the original version of the amendment disqualified two types of art:

1) that "developed by the applicant singly or jointly with others," and
2) that "known to the applicant only by virtue of his or her employment."

Apparently, both types of disqualified prior art were to be limited to unpublished information.

However, the original version was objected to both by the American Intellectual Property Law Association (AIPLA) and the PTO as being vague and overly broad. In particular, the AIPLA proposed redrafting the original version of the bill because:

> We believe that [the original draft] in addition to modifying subparagraphs (f) and (g) of Section 102 of Title 35 might be interpreted as eliminating other prior art bars. Also, some of the words in [the original draft] are unnecessarily vague. The purpose of the amendment is to precisely define the needed remedy.[64]

The PTO's reason for supporting a revision was as follows:

> Drafting an appropriate provision . . . has proven to be an elusive and complex task [The original draft of the amendment to section 103] is too broad. It is not limited, for example, to exchanges of background information among co-workers in a single organization. [Under the original draft] [i]nformation learned from or transmitted to outsiders could be disqualified as prior art.[65]

Congress' own explanation of the differences between the original and enacted versions of the amendment to § 103 was that "the language in [the adopted version] is parallel to but also is more precise than the language of [the originally proposed version]. For example, [the enacted version] makes clearer that information learned from or transmitted to persons outside the inventor's immediate organization is not disqualified as prior art."[66]

Thus, the enacted version of the amendment to § 103 (now § 103(c)) disqualifies "subject matter developed by another person" if it meets the following criteria:

1) it falls only within the definitions of sections 102(g) or (f); and
2) the subject matter of the prior art and of the claimed invention were:

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[60] *See Section by Section Analysis: Patent Law Amendments of 1984, supra* note 7, at 5833.

[61] *Patent Law Improvements Act: Hearing on S. 1535 and S. 1841 Before the Subcommittee on Patents, Copyrights, and Trademarks of the Senate Committee on the Judiciary,* 98th Cong., 157 (1984) (prepared statement of John E. Maurer).

[62] *See* H.R. 4525, 98th Cong. (1983).

[63] *Id.*

[64] *Hearing on S. 1535 and S. 1841, supra* note 61, at 67 (prepared statement of Bernarr R. Pravel, president, AIPLA).

[65] *Id.* at 32 (prepared statement of Gerald J. Mossinghoff, Assistant Secretary and Commissioner of Patents and Trademarks).

[66] *Section by Section Analysis: Patent Law Amendments of 1984, supra* note 7, at 5833.

a) commonly owned,

b) "at the time the [second] invention was made."

When the PTO implemented § 103(c) by amending 37 C.F.R. § 1.104, it explained that common ownership by the same "person" or "organization" "would include circumstances where the ownership resided in more than one person and/or organization as long as the applications are owned jointly by the same owners."[67] In other words, for the § 103(c) exception to apply, there must be an identical "ownership entity" between the subject matter which would otherwise qualify as prior art under §§ 102(f) or (g) and the subsequent invention claimed in the later filed patent application. In other words, to receive benefit of § 103 (c), if the prior art subject matter was owned by companies A and B, then the subsequent invention must also have been owned by companies A and B at the time the subsequent invention was made.

This interpretation by the PTO of "commonly owned" appears to be consistent with Congress when it amended the original bill in order to" make clearer that information learned from or transmitted to persons outside the inventor's immediate organization is not disqualified as prior art."[68]

C. An Inventor's Own Prior Work as Prior Art Under 35 U.S.C. §§ 102(f) and 102(g).

Assuming that the holding in *OddzOn* is adopted by the Federal Circuit generally, it means that

> an invention, A', that is obvious in view of subject matter A, derived from another, is also unpatentable. The obvious invention, A', may not be unpatentable to a third party who did not receive the disclosure of A, but it is unpatentable to the party who did receive the disclosure.[69]

The standard enunciated in *OddzOn* is perhaps workable where the subject matter is derived from a non-inventor. However, it becomes problematic where the subject matter is derived from a co-inventor. For example, in our hypothetical, α, β and γ are co-inventors of the improvement (i.e., the Antigen A/ Adjuvant X composition), which is potentially obvious over the initial discovery of Antigen A by α and β. Since the second inventive entity (α, β and γ) is considered to be "different" than the first inventive entity (α and β),[70] the second inventive entity could be said to have derived subject matter (the initial discovery Antigen A) from the first inventive entity that renders the improvement obvious when combined with other prior art documents.[71]

Thus, an important unanswered question is whether the Federal Circuit's holding in *OddzOn* would apply to communications between inventors.[72] In 1982, the Fifth Circuit in *Shields* v. *Halliburton Co.*[73] held that the prior work of one inventor does not constitute prior art against a later joint invention between the inventor and another.[74] In reaching this conclusion, the Fifth Circuit relied heavily on the fact that no patent had been filed directed to the first inventor's initial discovery.[75] While

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[67] Final Rules for Miscellaneous Patent Provisions, *supra* note 25.

[68] *Section by Section Analysis: Patent Law Amendments of 1984, supra* note 7, at 5833.

[69] *OddzOn,* 122 F.3d at 1403, 43 U.S.P.Q.2d at 1646.

[70] *See supra* note 7.

[71] Note that the § 103(c) exemption does not apply here since the "ownership entities" are also different—the initial discovery is solely owned by Company whereas the improvement is co-owned by Company and IP. See Final Rules for Miscellaneous Patent Provisions, supra note 25. This issue was discussed in greater detail above at pages 17–18.

[72] As indicated in note 24 *supra*, alliances between biotech partners have become an integral part of the industry. It is our view that applying the *OddzOn* decision to discussions between co-inventors at collaborating biotech institutions would serve to frustrate, rather than promote, discoveries in biotechnology in the same fashion as the decisions in *In re Bass* and *In re Clemens*, 622 F.2d 1029, 206 U.S.P.Q. 289 (C.C.P.A. 1980), decisions that many commentators, at the time, argued created a disincentive to file patents early and discouraged communication between co-workers at a single institution. The amendment to § 103 (which can now be found as § 103(c)) was made to legislatively overrule *Bass and Clemens. Section by Section Analysis: Patent Law Amendments of 1984,* supra note 7, at 5833. If the present day realities of biotech research had been known when Congress enacted the Patent Law Amendments of 1984, it is possible that the § 103(c) exemption would not have been limited to commonly owned inventions, but may have been extended to inventions arising out of collaborative research. *See* discussion *supra* pp. 17–18. The value of team research between present day collaborating biotech institutions is arguably as great as was the value of team research within corporations in 1984.

[73] 667 F.2d 1232, 216 U.S.P.Q. 1066 (5th Cir. 1982).

[74] *See id.* at 1235, 216 U.S.P.Q. at 1069.

[75] *See id.* at 1236, 216 U.S.P.Q. at 1069 ("Had Bassett sought a patent for his [prior] work . . . he must have claimed that process he had developed was an invention. Had Bassett then collaborated with Olsen, and sought a patent for their joint product they would have been declaring that their work constituted an invention. In such a situation each process would have

Chisum criticizes the rationale behind the Fifth Circuit's holding,[76] Chisum agrees that communications between co-inventors should not constitute prior art under § 102(f).

> In at least one instance derived knowledge should not be treated as "prior art." This is the case of joint invention. The prior knowledge in fact developed by a joint inventor as part of a prior invention should not be "prior art" under Section 102(f) as to the joint invention. This would be an exception to the normal concept of separate "inventive entities." Thus, the prior secret work of one joint inventor would be prior art as to the later invention of joint inventors only under Section 102(g)—which assumes reduction to practice and no abandonment, suppression or concealment.[77]

Arguably, applying the *OddzOn* standard to discussions between co-inventors at collaborating biotech institutions would serve to frustrate, rather than promote, discoveries in biotechnology.[78] This is particularly true since, in order to be joint inventors, there must have been some degree of collaboration among the inventors.[79] As the Fifth Circuit said in *Shields*, "if the first inventor's initial work . . . constitutes an earlier invention to any subsequent effort with a collaborator, no valid joint invention would be possible. Theoretically every joint invention would have to be the result of simultaneous inspiration of the collaborators."[80] However, like Chisum's admonishment of the Fifth Circuit's rationale in *Shields* on the grounds that § 102 "provides no basis for distinguishing between patented and unpatented prior invention insofar as the definition of 'another' is concerned,"[81] the patent statutes provide no basis for making a distinction between prior art under § 102(f) versus prior art under § 102(g) insofar as the prior work of one of the inventors is concerned.[82] In other words, we fail to see a statutory basis for the Federal Circuit to "carve out" an exception where an inventor's prior work qualifies as prior art under § 102(f), but not recognize a similar exception where the inventor's prior work qualifies as prior art under § 102(g).

In our hypothetical, since Company and Company-IP are different ownership entities and thus § 103(c) would not apply, obviousness issues could be presented under §§ 102(g)/103 against the improvement invented by α, β and γ based on the prior reduction to practice of Antigen A by α and β.[83] Thus, even if the Federal Circuit were to adopt Chisum's recommendation and recognize the exception that "knowledge developed by a joint inventor as part of a prior invention should not be 'prior art' under Section 102(f) as to the joint invention,"[84] patenting improvements arising out of collaborations between companies would still prove problematic unless this exception is extended to reach a joint inventor's previous reduction to practice that qualifies as prior art against the joint invention under § 102(g). However, if applied generally, the holding in *In re Bass*, discussed *supra*, would appear to militate

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to be the first of its kind. Accordingly, the validity of Bassett and Olsen's patent application would have to be established against Bassett's earlier one. However, as here, where Bassett does some work, seeks no patent, collaborates with Olsen, and subsequently they together seek a patent, the joint application declares that their work submitted as a whole is a single invention—the first of its kind. Because they declare their work to be single, and first invention, as between the joint inventors there is no earlier invention or prior art against which the joint invention need be established.").

[76] *See* 1 DONALD S. CHISUM, PATENTS § 3.08[2], at 3–155 (July 1998) ("It should be noted that the language of the relevant statute—Section 102—provides no basis for distinguishing between patented and unpatented prior invention insofar as the definition of 'another' is concerned. The holding in *Shields* could easily have been reached by either construing the prior unpatented work and later patented work as part of a single joint invention or by ruling that the prior work by 'another' was abandoned, suppressed or concealed within the meaning of Section 102(g).") (footnotes omitted). Construing an initial discovery by one inventor and an improvement resulting from a later collaboration as a single joint invention was the approach taken by the Sixth Circuit in *General Motors Corp.* v. *Toyota Motor Co.*, 667 F.2d 504, 212 U.S.P.Q. 659 (6th Cir. 1981), when considering a situation factually similar to that in *Shields.*

[77] *See* CHISUM, *supra* note 45, at 5–180 (footnotes omitted).

[78] *See supra* note 72.

[79] *See* Kimberly-Clark, 973 F.2d at 917, 23 U.S.P.Q.2d at 1926 ("[T]here must be some element of joint behavior, such as collaboration or working under common direction."); *see also infra* text accompanying note 20.

[80] *See* Shields, 667 F.2d at 1235, 216 U.S.P.Q. at 1069.

[81] *See* CHISUM, *supra* note 76, at 3–155.

[82] 35 U.S.C. § 103.

[83] Even though the first application filed in the U.S. by Company directed to the initial discovery is secret, filing a patent application can rebut a presumption of abandonment, suppression, or concealment. *See supra* note 51.

[84] CHISUM, *supra* note 45, at 5–180.

against recognizing such an exception to prior art under § 102(g)[85]. Thus, another important question is whether the holding in *In re Bass* creates a *per se* rule of unpatentability under §§ 102(g)/103 based on a joint inventor's previous reduction to practice.

In *General Motors Corp.* v. *Toyota Motor Co., Ltd.*[86], decided prior to the enactment of § 103(c), at issue before the Sixth Circuit was the obviousness of a catalytic converter that had been developed at General Motors (GM) in at least three stages. While citing *In re Land*[87] and *In re Bass*, Toyota argued that the "three steps are discrete inventions because the first two steps did not result from the collaboration of the patentees"[88] and thus the first two steps constituted prior art against the patented catalytic converter. GM countered with the argument that "there was only one invention, the patented converter, and the two earlier steps in its development should be seen as merging into the final product."[89] The Sixth Circuit sided with GM,[90] and "explained around" the CCPA's holdings in *In re Land* and in *In re Bass*:

> Neither Land nor Bass indicates that the prior inventions were in any way the product of concerted effort within a business entity. Under the facts of this case, where numerous "inventors" all worked under the aegis of one employer toward a common goal, it is appropriate to define the concept of joint invention broadly. It is not realistic to require in such circumstances that joint inventors work side-by-side, and that each step in the inventive process be taken by all the firm's collaborators.[91]

If it is not realistic to require that each step in the inventive process be taken by all the collaborators while working at a single institution, it is arguably even less realistic to require this where the collaborators are employed at different institutions. However, it is presently unclear whether the Federal Circuit would follow the Sixth Circuit's rationale in *General Motors* and extend it to situations involving collaborators working toward a common goal or goals while employed at different institutions. In our view, recognizing α and β's initial discovery as prior art under §§ 102(g)/103 against α, β and γ's improvement places an unreasonable burden on both Company and IP. It places Company in the unenviable position of having to decide whether to abandon, suppress, or conceal the initial discovery to better ensure that patent protection will be obtained for a potentially more commercially viable improvement and, for the same reason, gives the collaborating IP an incentive to seek such assurances from Company prior to entering into the collaboration agreement.[92] Further, creating a legal setting whereby the abandonment, suppression, or concealment of an initial discovery can, in certain circumstances, be beneficial runs contrary to a stated purpose of the patent system, which is to encourage the early disclosure of inventions to the public.[93]

In sum, it is our view that the prior art effect of the previous knowledge or previous reduction to practice of an inventor against a later joint discovery by the inventor and another remains uncertain. Important unanswered questions include whether the Federal Circuit's holding in *OddzOn* (that prior art under § 102(f) can be relied on in an obviousness determination under § 103) would apply to communications between joint inventors and whether the CCPA's holding in In re Bass cre-

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[85] The enactment of § 103(c) legislatively overruled *In re Bass* for situations where the initial discovery and the improvement were owned by the same entity at the time the improvement was made. *See supra* notes 66 and 68 and accompanying text, and note 72. However, where the initial discovery and the improvement were made at different institutions, it would appear that the holding of *In re Bass* still applies.

[86] 667 F.2d 504, 212 U.S.P.Q. 659 (6th Cir. 1981).

[87] 368 F.2d 866, 151 U.S.P.Q. 621.

[88] General Motors, 667 F.2d at 506, 212 U.S.P.Q. at 662.

[89] *Id.* "Put another way, GM contend[ed] that the patented converter is a "joint invention" of most or all of the above GM employees, and that an intermediate step by a subset of this inventive group should not be considered disabling prior art." *Id.*

[90] *See id.* ("GM's argument has the virtue of realism . . .").

[91] *Id.; see also, Clairol, Inc.* v. *Save-Way Industries, Inc.,* 210 U.S.P.Q. 459, 464 (S.D. Fla. 1980) ("The Court concludes . . . that Burian and Sempliner are joint inventors, and on the basis of this conclusion, holds that the Sempliner prototype is not prior art with the meaning of 35 U.S.C. § 103. Prototypes created by a co-inventor do not constitute prior art within 35 U.S.C. § 103.").

[92] While abandoning, suppressing, or concealing α and β's initial discovery would be helpful to avoid § 102(g) prior art against the improvement, it would be detrimental if applications relating to the invention are involved in an interference. In an interference context, the ability to rely on a prior actual reduction to practice for priority is lost if that actual reduction to practice is abandoned, suppressed, or concealed. Therefore, as a general strategy, it would be preferable to avoid § 102(g) prior art in ways other than relying on abandonment, suppression, or concealment.

[93] *See Hearing on S. 1535 and S. 1841, supra* note 61, at 157

ates a *per se* rule of unpatentability under §§ 102(g)/103 based on a joint inventor's previous work. In light of the present day reality that collaborative research between biotech and pharmaceutical institutions is an integral part of the industry, the Federal Circuit may want to consider recognizing the equity on a case-by-case basis of defining joint invention broadly to encompass the previous knowledge and work of each joint inventor, which would arguably be in agreement with, or at least a logical extension of, the Fifth Circuit's holding in *Shields* and the Sixth Circuit's holding in *General Motors*.

D. Recommendations

In our hypothetical, to avoid encountering potential obviousness rejections under § 102(f) and § 102(g), Company and IP should have at least considered an agreement whereby IP would contractually agree to assign its rights to all inventions arising out of the collaboration to Company. This would have invoked § 103(c) of the statute, which disqualifies § 102(f) and § 102(g) from use as prior art under § 103 if, at the time the improvement was made, the improvement and the initial discovery were "owned by the same person or subject to an obligation of assignment with the same person."[94] If such a common assignment or an obligation to assign the improvement to Company had been in place, § 102(f) and § 102(g) prior art issues based on the initial discovery would be resolved. (The Company patent attorney could then combine the first and second applications into a CIP to prosecute claims to both the initial discovery and the improvement in one application as we discuss in Section II above to avoid any § 102(e) issues.) Thus, from a patent law perspective, crafting collaboration agreements such that § 103(c) applies best ensures that claims are obtained to both the initial discovery and the improvement because, when prosecuting the improvement, it removes the obstacle of having to overcome an obviousness rejection on the merits based on the initial discovery.

However, from a business standpoint, agreeing to assign all inventions arising out of the collaboration to Company may not be acceptable to IP. This is because each joint owner (also called a co-owner or a tenant-in-common) is an owner of an undivided one-half interest in the patent[95] and is said to be at the mercy of the other joint owners.[96] The incidents of joint ownership are codified in 35 U.S.C. § 262 as follows:

> In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States without the consent of and without accounting to the other owners.[97]

Additionally, all co-owners must join in a patent infringement suit. Further, a "primary interest" of a co-owner is "the interest . . . in being able to license third parties under his or her patent without harassing suits by other co-owners."[98] Thus, clear advantages flow from being a joint owner of a patent, which may make IP reluctant to enter into an agreement assigning its rights to inventions arising out of the collaboration to Company. However, this notwithstanding, many of IP's concerns could presumably be addressed contractually, such as, for example, with an exclusive licensing arrangement.

Alternatively, to avoid having to fashion a licensing arrangement that compensates for IP's lack of ownership status, Company and IP could have agreed to assign Company's initial discovery and all inventions arising out of the collaborative research to a joint venture, incorporated by Company and IP especially for the purpose of the collaboration.[99] Another option would be for Company to agree, prior to the start of the collaboration, to assign to IP an undivided, one-half interest in any patent application directed to Company's initial discovery, with the assignment

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[94] 35 U.S.C. § 103(c).

[95] *Drake* v. *Hall,* 220 F. 905, 906 (7th Cir. 1915).

[96] *See* 5 E. LIPSCOMB'S WALKER ON PATENTS § 19:39 at 464–65 ("The tenant in common may make, use and sell specimens of the patented invention to any extent, and may license others to do so, and neither the tenant nor the tenant's licensees can be enjoined from a continuance in so doing. Nor can any recovery of profits or damages be had against such licensee at the suit of any co-tenant of any such licensor. And no recovery of profits or damages can be had against one co-tenant who, without the consent of the others, has made, used or sold specimens of the patented thing.") (footnotes omitted). *See generally* Robert P. Merges and Lawrence A. Locke, *Co-Ownership of Patents: A Comparative and Economic View*, 72 J. PAT. & TRADEMARK OFF. SOC'Y 586 (June 1990).

[97] 35 U.S.C. § 262.

[98] *Willingham* v. *Lawton, 555 F.2d 1340, 1344, 194 U.S.P.Q. 249, 252 (6th Cir. 1977).*

[99] This was previously suggested in an article by Virginia C. Bennett and Sorojini J. Biswas in *Protecting the patentability of your collaborative research*, 15 NATURE BIOTECHNOLOGY 472, 473 (1997).

conditioned upon the development of a patentable improvements from the collaboration. Thus, at the time of the invention of Antigen A/Adjuvant X, because of Company's obligation to assign rights in Antigen A, and due to the collaboration in the development of Antigen A/Adjuvant X, both inventions would be under an obligation to be assigned to the same ownership entity: Company-IP. Therefore, under either alternative, at the time of the invention both the potential "prior art" under § 102(f) or (g)/§ 103 of Antigen A, and the improvement invention of Antigen A/Adjuvant X would be under an obligation of assignment to the same ownership entity, and would fall within the exception in § 103(c). However, one caveat of both alternatives is that Company may not be willing to share its rights in Antigen A with IP for only the possibility of the development of valuable improvements from the collaboration. Thus, none of the alternatives we have discussed completely abrogate the § 102(f) or (g)/§ 103 prior art problem that plagues collaborations between companies.

IV. CONCLUSIONS

If a first patent application, directed to an initial discovery, and a later filed second patent application, directed to an improvement, do not name identical inventors, the disclosure of the first application may become available as prior art upon issuance into a patent against the second application under § 102(e). Thus, before permitting the first application to issue, the possibility of incorporating the text of both applications into a CIP that claims the initial discovery and the improvement should be considered. As a caveat, caution should be exercised before following this strategy in light of the traditional collaboration requirement for joint inventorship.

If the second application is assigned to a different ownership entity than the first application, §§ 102(e)/103 may apply as above against a claim to the improvement in the second application once the first application issues as a patent. In addition, §§ 102(g)/103 may also apply based on the prior reduction to practice of the initial discovery. This is because § 103(c) does not apply where the initial discovery and the later discovered improvement are not commonly owned, or at least under an obligation of common assignment, at the time the improvement is made. Further, if communications between co-inventors during the development of an invention can constitute prior art, §§ 102(f)/103 may also apply. While the law remains unsettled regarding the propriety of obviousness rejections under § 102(f) or § 102(g) based on a joint inventor's previous knowledge or work, we agree with others in recommending that the Federal Circuit recognize that prior knowledge developed by one inventor should not constitute prior art under § 102(f) as to later joint discoveries by the inventor and another. However, in our view, recognizing such an exception for § 102(f) but not for § 102(g) could promote the abandonment, suppression, or concealment of initial discoveries to avoid them from becoming secret prior art as to later discovered improvements arising out of the collaboration.

Strategies for ensuring that § 103(c) applies to collaborative research include having the industrial partner agree to assign all rights to inventions arising out of the collaboration to the company making the initial discovery. Alternatively, the company and the industrial partner could agree to assign the initial discovery and all inventions arising out of the collaboration to a joint venture, formed especially for purposes of the collaboration, or the company could agree to conditionally assign an undivided, one-half interest in its first application to the industrial partner.

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***This article reflects the present thoughts of the authors, and should not be attributed to Sterne, Kessler, Goldstein & Fox P.L.L.C. or any of its former, current, or future clients.

Mr. SMITH. Mr. Kushan?

STATEMENT OF JEFFREY P. KUSHAN, SIDLEY, AUSTIN, BROWN AND WOOD, WASHINGTON, DC

Mr. KUSHAN. Thank you, Mr. Chairman and Members of the Subcommittee, for the opportunity to share my views.

First, I would like to confirm that I am under 45. Laughter.]

That is the only significant confirmation that I have gotten in recent years of my age.

I would like to turn to the topic of the bill. What I hope to do in my testimony today is give you the perspective of somebody who is living in the patent community and looking at this issue, both from a procuring perspective of helping companies get patents, but also from a litigation perspective, either defending or attacking patents. That is an area which I think has significant risks for the community that works in the sector of biotechnology.

As has been explained, modern research today requires—it is not an option, it requires a vigorous and open community of scientists working together to develop inventions, to develop and advance the science. Biotech has been successful because this community has embraced openness. If you look at any biotech patent practitioner, one of the greatest stress factors they have is that their scientists, their inventors want to publish rapidly, which cause patent lawyers to age quickly because they have to get their patent applications filed or else they could lose rights. This climate is a critical feature of the success of the industry, however, and that is something which we want to preserve.

Our patent law recognizes that collaborations that produce useful inventions should get patents and those patents should sustain attacks. In the amendments that were made in 1984, that was the motivating factor. There was an environment of research where people worked for the same company, spoke to each other, and in that course of communication developed useful inventions. In 1984, the predominant model wasn't one which had your researchers going and dealing with other entities. As a result, you had an effect from this one decision which held that information that was communicated which was secret could somehow come in and raise the question of patentability of the patent that came out of the process of collaboration.

Now, in the bill you have introduced, there are two changes that are being proposed. I am going to focus on the first change, which is the change to 102(f). To get some context for this change, I thought I would give you a bit of background on the law.

Right now in our patent system, an inventor cannot obtain a patent on an invention that is obvious over the prior art. The prior art is the body of information which is publicly accessible. In our statute under 103, it says that you compare the invention that is the basis of the patent application to the prior art. In other words, it is designed to measure your invention against public information.

In the setting of prior art, the most predominant kind of prior art is something you might find in a patent or another scientific publication. It might be something that is put up on the Internet. This is all publicly accessible information. We have other kinds of information that is prior art because it is public. For example, if an inventor develops an invention and doesn't keep it a secret so that it becomes accessible to the public, then that can also be prior art against which inventions are going to be measured. Section 102(g) is the section of our law that says that information, that first invention can act as a barrier to another party getting a patent if it is an obvious variation.

There are also other instances of public information, public knowledge within the United States operating as a bar to patentability. Public knowledge that isn't in a patent or a printed publica-

tion outside the United States can't qualify to defeat a patent directly or because it would render the invention obvious.

This is an important distinction. Right now in our law, and particularly after the confirmation of our law in *OddzOn*, there is an effect given to one body of information which has traditionally not been viewed as public. Section 102(f) concerns secret information. It is information that if it was in a patent or if it was not kept as a trade secret would come in under another part of our law and block the granting of patents. If it is only information that can qualify under 102(f), it is secret. Nobody knows about it. It is secret information which is communicated. And this puts into question the basic balance of our patent system.

If you look at Section 102(f) or 102(g), the requirement for inventions to have entitlement to patents, that provision says that if you suppress or conceal your invention, then you have the risk, you raise a risk of somebody else patenting your invention. If you do not suppress the information, then you can come out and block another party's ability to get a patent, and this is where squarely we look at the issue of 102(f).

What we have in front of us is a piece of legislation that would remove the secret information from raising a question of risks to patents that issue from that collaborative environment.

And just to sum up, I want to make one last point. We tried to measure how frequently this issue is going to come up. I think the proper perspective is not to look at how many times this type of a scenario might arise. It is looking at it from the perspective of litigation involving a patent once you have successfully developed an invention, when there are lots of motivations to go back 15 years before the invention was made and the patent was granted, talk to everybody who talked to the first researcher and find out if somehow they had information that they shared with the person who actually got the patent. This creates an unsustainable risk to patent validity that we think we should remove.

Thank you, Mr. Chairman.

Mr. SMITH. Thank you, Mr. Kushan.

[The prepared statement of Mr. Kushan follows:]

PREPARED STATEMENT OF JEFFREY P. KUSHAN

Mr. Chairman and Members of the Subcommittee:

Thank you for providing me with the opportunity to express my views on a proposal to amend the patent law as it pertains to certain collaborative research settings.

I am a partner in the law firm of Sidley, Austin, Brown and Wood. Since 1987, I have held a variety of positions, in the Government and in private practice, that have exposed me to a broad variety of challenging questions in patent law, practice and policy. For many years, I was affiliated with the Patent and Trademark Office, first as a biotechnology patent examiner and later as an attorney in the Office of Legislative and International Affairs, where I worked on domestic and international patent policy issues. I have had the benefit of working with and representing inventors in companies, universities and the public sector in nearly all technological fields. The majority of my current clients are companies and research institutions in the biotechnology, pharmaceutical and software industries. My comments today, however, reflect my own views and should not be attributed to my firm or its clients.

SUMMARY OF POSITION

Collaborative research projects between the public and private sectors are an extremely important source of new technology that help to deliver valuable new products and services to the public. Our patent system should promote these collabora-

tions, and ensure that patents on useful inventions arising out of these collaborations are safe from unwarranted and unjustified challenges. At the same time, our patent system must provide certainty to inventors, businesses, investors and the public.

The proposed amendment to 35 U.S.C. 102(f) would eliminate deterrents to collaborative research projects by ensuring that confidential information exchanged by members of a research team from different institutions cannot be used to attack the validity of patents on inventions made by one or more members of that research team. The proposed amendment to 35 U.S.C. 103(c) would adopt a more objective standard to govern eligibility of the "safe harbor" against obviousness findings created by § 103(c) for parties engaged in a collaborative research project. The amendments have significant value because they will reduce uncertainty in the patent law as it pertains to the modern multidisciplinary research environment, and will remove potential clouds on patents that have already issued from collaborative research settings. Consequently, I strongly support the amendments in the proposed legislation.

BACKGROUND AND HISTORICAL CONTEXT

To be patentable, a claimed invention must be both novel and non-obvious over the "prior art." The prior art is the body of public information against which inventions are measured. Section 102 of title 35, United States Code, defines several types of information as evidence of "prior art." The two most common forms are patents and printed publications, such as technical journals. Evidence of the prior art also includes other types of publicly available information, including certain information that is "known" in the United States, even if it is not captured in a patent document or a publication. Certain information that is not "public" when it is created, but will become public at a later date, also forms part of the prior art. For example, information in a patent application that is published or granted as a patent forms part of the prior art as of the filing date of the patent application, even though at that time the information will not be accessible to the public.

Congress has also determined that certain acts or circumstances can disqualify a patent applicant from receiving a patent, regardless of whether the acts or circumstances are publicly known. The patent law thus defines several "loss of right" provisions that bar the patenting of inventions in specific circumstances, including:

- abandonment of the invention by the applicant;
- prior foreign patenting of the invention by the applicant in certain circumstances; and
- sale of the invention more than one year prior to the filing of the patent application.

In addition, Section 102(f) of title 35 provides that a person shall be entitled to a patent unless "he did not himself invent the subject matter sought to be patented." When this language was introduced in the 1952 Patent Act, it served the simple purpose of ensuring that the "person" who would be entitled to receive a patent would be the "true" inventor. As such, it was believed by many to be comparable to the "loss of right" provisions and not a definition of "public" information equivalent to prior art. There was and is a sound basis for this view—the circumstances where only § 102(f) is implicated by definition are those where the "information" is not public (i.e., it is not described in a patent or printed publication, was not sold a year before the patent was filed, and is not publicly known or in public use in the United States). If the information is "public" in these ways, other provisions of the patent statute operate to prevent the issuance of the patent on the invention.

Section 102(f) also is focused on derivation of the *same* invention. As the Federal Circuit held in *Gambro Lundia AB* v. *Baxter Healthcare Corp.:*

> "[T]he district court concluded that [the party challenging the patent] did not need to prove communication of the entire conception, but rather only so much of the invention "as would have made it obvious to one of ordinary skill in the art." . . . Based on this reasoning, the district court applied the obviousness standard in 35 U.S.C. § 103 (1994) to determine that the named inventors received enough information to make the invention obvious. . . . This reasoning, however, . . . introduces incorrectly an obviousness analysis into the test for derivation [under 35 U.S.C. § 102(f)]").

Thus, courts have not treated § 102(f) in a manner equivalent to the "prior art" provisions of the patent statute. Section 103 provides that a patent may not be granted on an invention that is obvious from the prior art. Specifically, § 103(a) specifies:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented [the invention] *and the prior art* are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Section 103 thus focuses on the differences between the invention claimed in a patent and the *prior art*. Section 103 historically has not evaluated the claimed invention against information that is not "prior art" (i.e., information that may be evidence only under the "loss of right" provisions of § 102). Thus, if an inventor abandons an invention (pursuant to § 102(c)), there is no barrier in our law against that inventor gaining a patent on an "obvious" variation of the abandoned invention if there is no prior art relevant to that invention.

TREATMENT OF PRIOR INVENTIONS BY OTHERS AND THE "PUBLIC BARGAIN" OF THE U.S. PATENT SYSTEM

Our patent system places a priority on protecting a "first inventor" who does not abandon, suppress or conceal his invention. Thus, under section 102(g) of title 35, a first inventor who does not abandon his invention, or keep it as a trade secret, can prevent another party from obtaining a patent. This can be done by any first inventor who files a patent application pursuant to 102(g)(1), or by a first inventor who, pursuant to section 102(g)(2), can establish that the invention was made in the United States, and not abandoned or kept as a trade secret, before another has invented the same invention or an obvious variation of it.

Congress has elected to limit the protection in our patent law for "first" inventors, however, to those who file patent applications on their inventions, or elect to make their inventions in the United States. Congress also has elected to limit the patent defeating effect of public information that is not captured in patents or printed publications. For example, information that is publicly known in other countries but is not captured in a patent or printed publication cannot bar the issuance of a U.S. patent for that invention or something which is obvious from it. Similarly, the sale of an invention in another country more than one year before a patent application is filed cannot bar the patenting of the same invention or an obvious variation of it in the United States. By contrast, public information or prior sale of the invention in the United States can bar the patenting of the invention or its obvious variation in the United States. Thus, under current U.S. law, a party could travel to Europe, purchase a device, modify it in an obvious manner and receive a patent on it.

PAST CONGRESSIONAL ACTION TO PROMOTE COLLABORATIVE RESEARCH

As noted above, § 102(g) provides that a person shall not be entitled to a patent for an invention that was made by another before the filing date of the application in question and was not "abandoned, suppressed, or concealed." Initially, this section was believed by many to be a "loss of right" provision—not a provision that defined evidence of the prior art. In 1973, however, the Court of Customs and Patent Appeals, in the decision of *In re Bass*, held:

> In view of the foregoing decisions and principles, we rule against appellants and hold that the use of the prior invention of another who had not abandoned, suppressed, or concealed it under the circumstances of this case which include the disclosure of such invention in an issued patent, is available as "prior art" within the meaning of that term in § 103 by virtue of § 102(g).

The court found that information about prior inventions that was secret at the time the invention in question was made—including information exchanged but held in secret by collaborative research partners—was "prior art" and could be used to deny or invalidate a patent.

This holding had profound consequences for those engaged in collaborative research projects. Under *Bass*, an invention developed by one employee of a company could render a later, obvious variation of that invention obvious—and thus unpatentable—despite the fact that all of the inventors worked for the same company and the earlier invention had not been disclosed to the public. Essentially, collaborative research partners found themselves in a dilemma. If they exchanged confidential information to spur further innovation among their research team, or added inventors to a research project, they placed in jeopardy patents on "later" inventions arising out of the continuing research collaboration.

Recognizing the importance of promoting team research, and the illogical and adverse effect of the *Bass* decision relative to the then-prevailing model for research,

Congress enacted amendments in 1984 to partially overrule *In re Bass*. It did so by creating a "safe harbor" from findings of obviousness through the addition of the following language to § 103 of title 35:

> Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

The 1984 amendments "immunize" patents from challenge under § 103 where all the members of a research team that produced the invention, at the time the invention was made, worked for the same entity or had assigned their rights to the same entity. Section 103(c) does so by holding that a patent may not be refused or invalidated as being obvious in view of information specified in sections 102(f) or (g), or, since amendments in 1999, information in earlier-filed patents pursuant to section 102(e).

In enacting the 1984 amendments, it was recognized that the public interest would not be served by refusing or invalidating patents on the basis of *non-public* information that was communicated among members of a research team. The "safe harbor" Congress created, however, was limited to situations where all of the researchers had transferred their rights in any invention developed by the team to a single legal entity. The requirement for common assignment or ownership ensures that all patents granted on the basis of this exception to the nonobviousness requirement will be controlled by a single entity. Thus, a third party that licenses a first patent will not have to face demands from an unrelated entity over a patent granted solely as a result of § 103(c) for an invention that is only an obvious variation of the invention claimed in the first patent.

It was also recognized that the public interest would not be served by allowing anyone—whether a single inventor or a large corporation—to use the new exemptions of § 103 as a "Trojan Horse" to enable the independent patenting of an endless series of minor or "obvious" variations of the same basic inventive concept—thereby obtaining an extended period of patent protection for these "obvious" inventions. The 1984 amendments thus endorsed the PTO practice of rejecting claims in commonly-owned applications that were "obvious" over each other under the judicially created doctrine of non-statutory (or "obviousness-type") double patenting. The effect of such practice was to ensure that all of the "obvious" variations of the first invention would enjoy the same term of protection as the original—and thereby avoided the possibility of extending the term of protection of the first patent in the series. The "non-statutory" double patenting standard, which has since been further developed by the Federal Circuit, remains an important feature of our patent system that serves to protect the public interest.

THE ODDZON DECISION CONFIRMS THE SCOPE AND EFFECTS OF THE 1984 AMENDMENTS

The Federal Circuit's opinion in *Oddzon* brought into focus certain problems that can arise when collaborators working for different legal entities exchange confidential information. In particular, the Federal Circuit resolved the question of whether non-public information exchanged between two parties that qualifies only under § 102(f) can be used in conjunction with "conventional" prior art to render a claimed invention obvious. In its opinion, the court stated:

> It is historically very clear that [current § 103(c)] was intended to avoid the invalidation of patents . . . on the basis of the work of fellow employees engaged in team research. *See Section-by-Section Analysis: Patent Law Amendments Act of 1984,* (stating that the amendment, *which encourages communication among members of research teams*, was a response to *Bass* and *In re Clemens*, in which "an earlier invention which is not public may be treated under Section 102(g), and possibly under 102(f), as prior art"). *There was no clearly apparent purpose in Congress's inclusion of § 102(f) in the amendment other than an attempt to ameliorate the problems of patenting the results of team research. However, the language appears in the statute; it was enacted by Congress. We must give effect to it.*

The court's comments regarding the inclusion of § 102(f) within the safe harbor of § 103(c) reinforces perceptions that are commonly held in the patent community. Many patent practitioners believe that confidential communications that fall only within § 102(f) should not form part of the "prior art" because they are not "public" and should not be capable of rendering an invention "obvious" within the meaning of § 103.

The Federal Circuit also recognized that the literal effect of the 1984 amendments was inconsistent with the "solution" that Congress had devised, as well as with the prevailing understanding that the patent bar attached to information that qualifies as "patent-defeating" only under § 102(f). It even went so far as to invite Congressional review of the 1984 amendments, stating:

> It is sometimes more important that a close question be settled one way or another than which way it is settled. We settle the issue here *(subject of course to any later intervention by Congress or review by the Supreme Court)*, and do so in a manner that best comports with the voice of Congress. Thus, while there is a basis for an opposite conclusion, principally based on the fact that § 102(f) does not refer to public activity, as do the other provisions that clearly define prior art, nonetheless we cannot escape the import of the 1984 amendment.

The court then held that information that qualified as novelty defeating only under § 102(f) may properly be considered when determining whether the claimed invention is obvious under § 103. It also confirmed that the safe harbor of § 103(c) was limited to situations involving common ownership or assignment.

Two points should be appreciated about the *Oddzon* decision. First, the party that sought to invalidate the patent apparently was *not* the entity from whom the patentee had received any information. Thus, the *Oddzon* case did not implicate the public policy justifications for § 102(f) (i.e., to protect the "true" inventor from derivation of the same invention). Second, the information that was used to attack the patent was not publicly known and could not qualify as evidence of prior art under any other provision of the patent statute. Instead, the party that challenged the patent exploited the discovery of pre-filing communications to formulate its attack on the patent.

In my view, the Federal Circuit in *Oddzon* correctly construed § 103(c), despite the inconsistency of its substantive effect with the historical function and purpose of § 102(f). I believe it would be unlikely that the Federal Circuit would reach a different conclusion regarding the role of § 102(f) "information" in an obviousness determination if similar facts were presented to it today. As Judge Lourie indicated in the court's opinion, even though the plain language of the statute is inconsistent with the traditional view of the role of § 102(f), § 103(c) as written permits the use of information that qualifies only under § 102(f) to serve as the basis of a finding of obviousness under § 103 if there is no common ownership or assignment obligation.

ISSUES AND CONCERNS ADDRESSED BY THE PROPOSED LEGISLATION

Testimony offered last year by the university community cited a number of concerns with the state of the law after the 1984 amendments and the *Oddzon* opinion. Most of these concerns focused on the inability of universities and their private sector partners to create the legal structures that are needed to qualify for the "safe harbor" of § 103(c). I believe that these concerns are legitimate. I also believe other significant problems exist with the state of the law after *Oddzon*. The most significant of these is the potential that the current state of the law creates for abuse in the patent litigation environment. Correcting these problems will require amendments to the patent law that eliminate the ability of confidential information that cannot qualify as prior art from being used in obviousness determinations.

Before discussing the concerns that justify legislative action, I believe it is important to appreciate when problems under sections 102(f) and 103 can arise for *bona fide* collaborations. First, an *Oddzon* situation can arise only where § 102(f) alone is implicated. The most common situation will be where a first researcher (A) communicates confidential information to a second researcher (B), but where this occurs before A and B have created the necessary legal relationship to qualify for the safe harbor of § 103(c). If the information being transferred from A to B is not confidential—meaning that B can learn of it from an independent source—other provisions of the patent statute will govern whether B can get a patent. Second, an *Oddzon* situation can arise only where A is not named as one of the inventors on the patent. If A and B are named as joint inventors, there can be no claim of "derivation" within the meaning of § 102(f) because both A and B will own the patent. Thus, an *Oddzon* situation can arise only where (a) there is no obligation for common ownership or assignment before the invention was made, (b) one party in a research team conveys information that, when combined with other prior art, would render the invention obvious, and (c) the party conveying that information is not part of the inventive entity named in the application. Unfortunately, this situation arises frequently in university-research environments due to the restrictions of the Bayh-Dole Act which prohibit assignments of inventions without prior government approval. Moreover,

there often will be at least a basis for investigation into whether an *Oddzon* situation existed in the context of most patent disputes involving biotechnology companies, due to the open research environment that exists within this community.

As is evident from the comments of the university community, *Oddzon* creates real and significant problems. Universities are uniquely affected by *Oddzon* because, unlike private parties, they cannot freely assign their rights to inventions, particularly before an invention is "made." In particular, under the Bayh-Dole Act if the invention is made, in whole or in part, with Federal funds, universities may not freely transfer rights to any commercial entity. As a result, universities cannot create the legal structures that will qualify them for the safe harbor of § 103(c) for their external research collaborations. This is especially true before any invention has been "made" as a result of that collaboration.

The options available to a university and its private sector partner are extremely limited. For example, the private company could transfer all of its rights to any inventions arising out of the collaboration to the university partner in advance. Such options are extremely unattractive to most potential commercial partners. Businesses are usually reluctant to convey rights broadly and unconditionally before an invention with an identifiable commercial value has been made. Indeed, some companies simply reject the opportunity of working with universities, given the requirements of insulating the results of the research collaboration from future challenge under § 103.

The current law thus has the effect of arbitrarily distinguishing between classes of inventors. Researchers affiliated with organizations with the flexibility to create special legal relationships can readily protect the fruits of their collaborative efforts using the patent system, while those without that flexibility cannot. No sound policy reason supports making this distinction, especially in view of the immense public benefits of the modern and open research environment supported by the Bayh-Dole Act

The current state of the law also presents a new and unconstrained theory to be used to attack patents in litigation. Patent litigation already is notoriously complicated and expensive. *Oddzon* will make this already complex form of litigation even more complicated and expensive. This will be particularly true for those patents that were preceded by some form of a pre-filing interaction between the patent owner and an unrelated entity. For example, using the logic of *Oddzon*, if a party challenging the patent can identify any interactions between the research team that produced the invention and an unrelated party, it can pursue discovery seeking evidence of "102(f) prior art" to attack the patented invention as being obvious. Unlike a true "derivation" situation, the attack in such a case will be focused on discovery of "evidence" in the form of confidential communications that can be strung together to claim that the patented invention is obvious. These communications will not be publicly accessible, and most likely will take the form of statements of individuals members of the research team about events that occurred ten to fifteen years before the litigation.

In response to these concerns, some have alleged that *Oddzon* issues will arise infrequently, and therefore, there is no need for legislative action. This view is ill-founded. The chilling effects on collaborative research caused by the current law and the holding in *Oddzon* must be assessed other than by the number of patents actually invalidated through litigation.

As pointed out above, *Oddzon* risks for patents arising from university research are a very real possibility in many research settings. This means that *"Oddzon"* risks have to be evaluated routinely by research enterprises in today's business environment. For example, a company contemplating a research collaboration with a university must consider several unattractive options regarding co-ownership or assignment of rights to technology arising from the collaboration. Similarly, a company contemplating licensing a university patent must assess several additional risks of invalidity that may exist for that type of patent. Research and commercialization of an invention already is an inherently risky commercial exercise, particularly in the biotechnology and pharmaceutical sectors. When these inherent risks of commercial development are coupled with the additional risks of losing a patent due to an *Oddzon* situation, many commercial partners may elect to simply pursue other opportunities.

OBSERVATIONS ON THE CURRENT LEGISLATIVE PROPOSAL

The proposed legislation would effectively eliminate secret information that qualifies as prior art only under § 102(f) from rendering an invention "obvious" within the meaning of § 103. It also provides additional flexibility for parties to claim the benefit of the "safe harbor" of § 103(c), and does so in a way that will provide more

certainty than is provided under current law. The changes thus remove the risks created by the current law, but in a way that preserves the balance in our patent system of rewarding and protecting those inventors who either pursue their own patents or who elect to not conceal or abandon their inventions.

The proposed amendment to § 102(f) would specify that information qualifying only under this subsection is not "prior art" and cannot be evidence of obviousness of an invention within the meaning of § 103. As a consequence, information that could qualify only under § 102(f) could not be used in combination with prior art to render an invention obvious under § 103. The amendment would restore § 102(f) to the "non-prior art" status it had in the patent law prior to the 1984 amendments that created what is now § 103(c).

The amendment does not alter the law governing § 102(f), standing alone. If a first inventor conveys information concerning an invention to a second party, that second party will not be able to obtain a patent on the same invention. This will not change under amended § 102(f). The amendment thus leaves intact the law and jurisprudence that serves to prevent derivation of inventions.

The legislation will leave intact current law governing novelty and nonobviousness other than in the specific instance of information governed solely by § 102(f). As a result:

- prior inventions made in the United States or that are claimed in a patent application, and that are not suppressed, abandoned or concealed, may be used to refuse or invalidate a patent on a later invention that is obvious from that first invention, unless the later invention qualifies for the existing safe harbor of § 103(c); and
- evidence of prior knowledge, use or sale of subject matter within the United States that would render the invention obvious remains available to refuse a patent or render it invalid, whereas such knowledge or sale outside the United States will not, as is the case today.

I believe the proposed amendment to § 102(f) is fully consistent with the public policy that underlies our patent system. It corrects what appears to be a legislative oversight in the 1984 amendments that converted information that qualifies solely under § 102(f) into "prior art" rather than preserving the status of § 102(f) as a "loss of right" provision. Since information that qualifies only under § 102(f) is not publicly accessible and does not form part of the body of "public information," it should not be capable of gaining status as "prior art." The amendment is also consistent with the primary goal of our patent system to promote public disclosures—rather than secrecy—of patentable inventions.

The legislation also proposes to change the critical date in § 103(c) to the date a patent application is filed, rather than the date the invention "was made." This change will improve certainty in the patent law by providing an objective standard for measuring eligibility for § 103(c). It will help all potential patent applicants by providing more time for members of a team research project to assess the value of an invention before having to create special common ownership arrangements.

The changes made by the legislation would apply to patent that are in existence on the date of enactment, or are issued on or after the date of enactment. The effective date provisions provide, however, that the changes will not alter rights or obligations that exist among parties that are engaged in administrative or judicial proceedings. Thus, a patent that is involved in litigation, or a patent application involved in an interference proceeding before the Patent and Trademark Office, prior to the date of enactment will be governed by current law. The effective date provisions of the bill have significant value, because they eliminate risks to patents that exist today.

The amendments to sections 102(f) and 103(c) will resolve many of the concerns that have been raised about the state of the law governing inventions resulting from team research. One practical effect of the changes will be to make private and confidential communications among researchers irrelevant to determinations of patentability under § 103. This will remove a potential cloud over patents where there have been pre-assignment communications among researchers from different entities. The amendments also will give universities and private entities more time to create the legal structures that are required to claim the safe harbor of § 103(c). Since such structures cannot be created in advance under the Bayh-Dole Act, and the alternatives are unattractive to the private sector, the new standard will provide options that are not possible today. These options, I believe, will promote the development and commercialization of inventions arising out of research collaborations that have discrete and tangible value.

Last year, the Subcommittee heard the views of several individuals and organizations on proposals to amend § 103(c) of title 35, United States Code. Some of the

proposals then under discussion would have amended § 103(c) to give "research collaborations" a status equal to common ownership or assignment of rights to an invention under the statute. Testimony at last year's hearing reflected a number of concerns over that approach to resolving the concerns over the *Oddzon* decision.

For example, some opposed the concept of amending § 103(c) to equate "research collaborations" with situations of common ownership and assignment. Such changes, it was feared, would introduce more uncertainty into an area that already suffers from excessive confusion. It was also suggested that a "loosened" § 103(c) standard could give rise to new types of double patenting problems, or could create undesirable situations such as two patents issued to separate entities on inventions that were mere obvious variations of each other.

The current proposal effectively addresses the concerns that were expressed last year.

- The current proposal does not depart from the requirement of common ownership or assignment as found in current section § 103(c). As a result, no issues arise regarding the difficulties of defining what constitutes a "research collaboration" or how courts would deal with such a definition.
- Under the amended standard, § 103 will continue to prevent multiple patents from issuing to different legal entities on "obvious" variations of an invention where there has been no common assignment or ownership of the invention. It does so by continuing to preserve the ability of a first inventor who has not abandoned, suppressed, or concealed an invention to prevent another party from obtaining a patent on an obvious variant of that invention. If the first and second parties both file patent applications, only one will obtain a patent, as is the case today.
- No new issues of "double patenting" will arise under the amended standard. This is because in situations where only 102(f) is implicated, there will be no "other patent." If there is another patent, section 102(e) will prevent the issuance of a later patent on an obvious variation of that first patent.

Thus, the legislation effectively responds to the concerns voiced last year.

I commend the Subcommittee for taking steps to improve the collaborative research and development environment in the United States. The proposed amendments will improve certainty in operation of the patent law, and will resolve many of the concerns voiced by the university community last year. If enacted, the legislation will promote research among the university and private sector, primarily by removing disincentives and risks that would otherwise deter such cooperation.

Thank you for the opportunity to express my views.

Mr. SMITH. Professor Thomas?

STATEMENT OF JOHN R. THOMAS, PROFESSOR OF LAW, GEORGETOWN UNIVERSITY LAW CENTER, WASHINGTON, DC

Mr. THOMAS. Thank you, Mr. Chairman. I appreciate the opportunity to appear before the Subcommittee. I have come in my personal capacity as a concerned observer of the patent system.

Let me recap by stating that to understand the purposes of the CREATE Act, an overview of patent law fundamentals may be appropriate. For an invention to be patented, it must meet two fundamental requirements, novelty and non-obviousness. The novelty requirement is found in Section 102 of the Patent Act and it requires that an invention just be different, really just be basically different from what has come before. Section 102 also details in a lot of detail, and when I teach this section I call it the "long march" of all the different sources of knowledge that may be considered in these inquiries, things like patents, earlier publications, earlier public uses, and the sum of this knowledge, as you said, Mr. Chairman, is termed the prior art.

Now, one of the seven paragraphs of Section 102, paragraph (f), prevents a patent from issuing to an applicant who did not himself invent the subject matter sought to be patented, and this makes a lot of sense. Only the true inventor ought to apply for a patent and

receive one. If the patent applicant merely derived that information from another, he shouldn't be awarded a patent. We ought to get the true inventor having the patent.

Now, importantly, for Section 102(f) to defeat a patent, the patent or patent application must be identical to what was disclosed. That is the anticipation or novelty requirement. Generally speaking, even a small variation will block the use of Section 102(f).

Section 102(f) is infrequently used because as a predicate to derived information from another, that other person must have invented it first. So usually, one of those provisions that speaks to the first inventor getting the patent will apply. So Section 102(f) is generally limited to trade secrets, which don't count as prior art under another provision, and foreign oral disclosures, disclosures that occurred overseas but were not written down. Those also don't count as prior art under any of the other Section 102 paragraphs.

Now, as we have heard, Section 102(f) applies to non-obvious through the *OddzOn* case. The second fundamental requirement of patenting is non-obviousness. This allows the combination of references to be employed or one teaching with stirring in the knowledge of the prior art. In Section 102(f), it can be an input to non-obviousness. Derived information is evidence under current law of non-obviousness or not.

Now, so much for the basics. What about the CREATE Act? When considering the consequences of the CREATE Act, it is important to remember that the patent law was all about incentives, and what are some of the incentives that the CREATE Act might cause?

Well, first, the CREATE Act might encourage innovative individuals to make their inventions publicly available in the United States by publishing, by patenting or some other mechanism. If they don't, then another individual might come along, make a minor variation, and be able to obtain a patent on that invention. This effect comports with the general notion of the patent law that we want people to publish. We want people to disclose their innovations.

However, the CREATE Act might also have a "listen but don't talk" effect. On the other hand, it may make inventors less willing to collaborate out of fear that others will take what has been disclosed to them, make a minor modification, and then seek patent protection themselves, although there are other mechanisms in the patent law for the original inventor to claim that she is the first inventor, such as provoking interference or claiming that she should be a joint inventor. Those are more costly and may not be available in all circumstances.

The CREATE Act might also encourage individuals to go abroad, listen to all disclosures, bring that disclosure back in this country, make a minor modification, and obtain a patent. This arrangement effectively would resurrect the old English notion of a patent of importation, which were granted not to the first inventor, but for the first person who brought a technology into the realm.

I also observe that by expressly excluding Section 102(f) from non-obviousness considerations, that would be the only one of seven paragraphs of Section 102(f) that says it doesn't apply to obviousness. The negative implication is that all the other paragraphs do

apply for non-obviousness determinations. That is pretty much what the courts do right now, but there are a couple of the more obscure sections of 102, Section 103(c) and (d), where the Federal Circuit has said in dicta do not apply to non-obviousness. So, in effect, this bill might not only overturn the principal holding of the *OddzOn* case, it might overturn the dicta, too.

Finally, it is important to remember that sometimes one prior art reference, like a scientific publication or a patent, applies under more than one paragraph of Section 102(f). So I think you would want to stress that if a reference was available under another paragraph of Section 102, as well as 102(f), that it would apply as prior art. So you could add the word "exclusively" into Section 102(f) to avoid this difficulty.

Thank you very much.

Mr. SMITH. Thank you, Professor Thomas.

[The prepared statement of Mr. Thomas follows:]

PREPARED STATEMENT OF JOHN R. THOMAS

I appreciate this opportunity to appear before the Subcommittee. I have come today in my personal capacity as a concerned observer of the patent system.

The Cooperative Research and Technology Enhancement Act of 2003 (the CREATE Act) succinctly provides that prior art available under 35 U.S.C. § 102(f) may not be considered as evidence of obviousness under 35 U.S.C. § 103. The effect of the Act is to overturn the 1997 holding of the U.S. Court of Appeals for the Federal Circuit in *OddzOn Products, Inc.* v. *Just Toys, Inc.*,[1] which ruled that derived prior art may serve as evidence of obviousness.

To understand the impact of the CREATE Act, an overview of some patent law fundamentals may be appropriate. For an invention to be patented, it must meet two fundamental requirements: novelty and nonbviousness. The novelty requirement, stipulated in § 102 of the Patent Act, requires that the invention differ from earlier knowledge. Section 102 details which knowledge—such as earlier patents, publications and public uses—may be considered in this inquiry. The sum of this knowledge is termed the "prior art" in patent parlence.

One of the seven paragraphs of § 102, paragraph (f), prevents a patent from issuing to an applicant who "did not himself invent the subject matter sought to patented."[2] This provision presents something of a standing requirement, mandating that only the true inventor apply for a patent. If a patent applicant merely derived the invention from another person, then he should not be awarded a patent. A *prima facie* case of derivation entails a showing of another's prior conception of the claimed subject matter along with an awareness of that conception by the applicant or patentee.[3] Importantly, to defeat a patent or patent application, the derived information under § 102(f) must be identical to the claimed invention. Generally speaking, even a small variation will block the use of § 102(f).

Section 102(f) is not often used in patent acquisition proceedings at the U.S. Patent and Trademark Office (USPTO). Even in adversarial proceedings, such as interferences and enforcement litigation, the courts have not employed § 102(f) with great frequency. The scarce use of § 102(f) results from the fact that a predicate to derivation is that another person first invented the subject matter sought to be patented. As a result, another prior art provision, such as § 102(a), ordinarily applies to such cases.[4] Parties adverse to the patent generally will find proofs of patent invalidity more straightforward under § 102(a), which does not entail the nettlesome issues of communication and copying.

As a result, § 102(f) is most often employed in factual circumstances where § 102(a) does not apply. In particular, § 102(f) is not limited to inventions conceived "in this country," nor have courts imposed a requirement that the knowledge be

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[1] 122 F.3d 1396 (Fed. Cir. 1997).

[2] 35 U.S.C. § 102(f) (2000).

[3] *Price* v. *Symsek,* 988 F.2d 1187 (Fed. Cir. 1993).

[4] 35 U.S.C. § 102(a) (2000) denies a patent if "the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent. . . ."

publicly accessible as they have in § 102(a).[5] Paragraph (f) would be the only part of § 102 that would apply, for example, to oral disclosures that occurred abroad, or to derived knowledge that has been kept as a trade secret.

The second fundamental requirement of patenting, nonobviousness, is set out in § 103 of the Patent Act.[6] To be considered nonobvious, the invention must not have been within the ordinary capacities of a person of ordinary skill in the art.[7] Unlike the novelty requirement of § 102, a patent or patent application may fail to meet § 103 even though its subject matter is not identically disclosed in the prior art. A combination of different teachings, or even small changes from a single teaching, may be used to show that the invention would have been obvious.[8]

Section 102(f) relates to the nonobviousness requirement of § 103(a) in the following way. Section 103(a) does not expressly define which prior art may be considered when a court, or USPTO patent examiner, has to decide whether the invention would have been obvious. Generally speaking, the courts have filled this gap by holding that prior art described in § 102, including paragraph (f), serves as the basis for nonobviousness determinations.[9] USPTO regulations comport with these holdings.[10] Congress has also specified in § 103(c) that § 102(f) art is exempted from nonobviousness considerations if the prior art under § 102(f) and the claimed invention were either owned by, or subject to an obligation of assignment to, a single entity at the time the invention was made.[11] In essence, the CREATE Act would expand this limited exception, instead excluding § 102(f) art entirely from nonobviousness determinations.

Several possible consequences flow from the CREATE Act. First, the CREATE Act would encourage innovative individuals to make their inventions publicly available—for example, by publishing or patenting the invention—in the United States. If they do not, then another individual may make a minor modification to the disclosed invention and patent it himself. This effect comports with the general notion in patent law that prior art be publicly available, rather than secret knowledge.

On the other hand, the CREATE Act may encourage individuals to file patents on inventions that are obvious variations of derived information. For example, it would be possible for an individual to attend a technical conference overseas, listen to an oral disclosure of another's invention, and then obtain a U.S. patent claiming a minor variation of the disclosed subject matter. This arrangement effectively resurrects the old English notion of a "patent of importation" to the first person disclosing an invention domestically, even though that person was not the first inventor.[12]

It is important to note that the true inventor is not wholly without remedy in such circumstances. He may, for example, file a patent application and attempt to provoke an interference under 35 U.S.C. § 102(g)(1). However, this step may entail considerable costs that § 102(f) did not. Note also that the true inventor may not be able to prove that he is the first inventor outside of interference proceedings, due to the fact that his activities did not occur "in this country" under the language of 35 U.S.C. § 102(g)(2).

In this vein, it does not appear that the CREATE Act works towards international harmonization of the patent laws. Consider Article 54(2) of the European Patent Convention, which provides:

> The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

Under European Patent Convention, subject matter derived from foreign oral disclosures counts as prior art, while under the CREATE Act it may not.

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[5] *See OddzOn Products, Inc.* v. *Just Toys, Inc.* 122 F.3d 1396 (Fed. Cir. 1997).

[6] Under 35 U.S.C. § 103(a) (2000):

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

[7] 35 U.S.C. § 103(a).

[8] Roger E. Schechter & John R. Thomas, Intellectual Property: The Law of Copyrights, Patents and Trademarks 370 (2003).

[9] *OddzOn Products, Inc.* v. *Just Toys, Inc.* 122 F.3d 1396 (Fed. Cir. 1997). According to the *OddzOn* court, prior art under paragraphs (c) and (d) of § 102 does not apply to nonobviousness determinations under § 103(a).

[10] 37 C.F.R. § 1.106(d).

[11] 35 U.S.C. § 103(c) (2000).

[12] *See* Martin J. Adelman *et al.*, Patent Law: Cases and Materials 427–28 (2d ed. 2003).

In terms of cooperative research, the CREATE ACT may make innovators more willing to make use of discussions with their colleagues in future work. On the other hand, it may make innovators less willing to collaborate, out of fear that others will modify their inventions and obtain patent protection on them. This concern is less pressing for domestic than foreign inventors, as a U.S.-based inventor would be able to demonstrate prior inventorship under 35 U.S.C. § 102(g)(2). In addition, both foreign and domestic inventors may be able to claim status as joint inventors under 35 U.S.C. § 116.

I also observe that by expressly excluding § 102(f) prior art for nonobviousness, the CREATE Act implies that prior art available under the six remaining paragraphs may be consulted for purposes of § 103. This result largely comports with current case law of the U.S. Court of Appeals for the Federal Circuit and its predecessor courts. However, it should be noted that in the *OddzOn* case, the Federal Circuit stated in dicta that two of the more obscure paragraphs of § 102—the public abandonment bar of paragraph (c) and the delayed U.S. filing bar of paragraph (d)—did not apply to nonobviousness.[13] The CREATE Act may well be considered to have overturned the *dicta* of *OddzOn* as well.

Finally, it is important to remember that sometime one prior art reference—such as a scientific journal article—may be described by more than one paragraph of § 102. Congress may wish to specify that prior art that is available under both § 102(f) and another paragraph of § 102—for example, the statutory bars of § 102(b)—may be consulted during the nonobviousness inquiry of § 103. Put differently, the CREATE Act could be amended to specify that § 102(f) prior art may not be considered for purposes of nonobviousness only if that subject matter is prior art exclusively under § 102(f).

Thank you for hearing my testimony. I would be delighted to answer any questions.

Mr. SMITH. Thank you all for pointing out how important this kind of collaborative research is to the economy and for supporting what we are trying to do with this legislation, which is to eliminate some of the concerns that we have about the *OddzOn* case, and that is much appreciated.

Actually, today's hearing is almost a quintessential example of what hearings are supposed to do, which is refine and tweak legislation to try to improve it, and you all have made several suggestions.

What I would like to do, Dr. Soderstrom, is to ask you and Mr. Kushan to respond to a couple of the suggestions made by Mr. Steffe and Mr. Thomas. Both Mr. Steffe and Mr. Thomas have mentioned Section 102(f). Professor Thomas, in your prepared testimony, you talked about some concerns you had about foreign inventors, as well, which I would like to go into in a minute.

And then, also, I don't want to leave you all, Professor Thomas and Mr. Steffe, in a position where you can't respond. What I want to do is get a discussion going among you four experts to see what we need to do.

But let me read from Mr. Steffe's written testimony, and it will be very precise in regard to that Section 102(f), and then ask Dr. Soderstrom and Mr. Kushan to respond initially, and then the others respond afterward.

This is Mr. Steffe's testimony. "In fact, I would go further than the proposed bill by removing mention of Section 102(f) from Section 103(c) and by amending Section 102(f) to read, 'A person shall be entitled to a patent unless he did not himself invent the subject matter sought to be patented, except that subject matter communicated from a co-inventor shall not be considered prior art under this subsection.' My proposal would address, among other things,

[13] *See OddzOn Products, Inc.* v. *Just Toys, Inc.* 122 F.3d 1396 (Fed. Cir. 1997).

the potential for pirates to file a patent application for an obvious modification of an invention misappropriated from another party. I believe my proposal more surgically addresses the drawbacks of the current Section 103(c) and mitigates unintended consequences."

Dr. Soderstrom, do you agree that that change would be necessary, and if not, why not, and if so, why?

Mr. SODERSTROM. Well, first of all, let me caveat, I am not a patent attorney. I am a practitioner and I certainly make use of them.

My reaction, having been on both sides of litigation, both defending and prosecuting patents, is that I think the difficulty that I see that the Act needs to deal with are the 103(c) issues, not 102. I think the problem I see is that when you start playing around with the language in 102, there are lots of other issues that arise that have unintended consequences that I fear we will be right back here trying to correct a year from now.

Mr. SMITH. Okay. Thank you. Mr. Kushan?

Mr. KUSHAN. Thank you. I think to respond to that question, I think we have to look at the type of environment which we are trying to shield by the amendments. I think it is important to appreciate that in the modern environment, what you have are two entities with lots of people working together. Some of those people are not going to be inventors. They are going to be speaking to each other, are going to be working together. There will be a flow of information. That is the idealized scenario that you are trying to create. You want an open, fluid communication process.

I think the change that has been proposed wouldn't capture the full scope of the scenario that we are trying to protect because it would still have a strong encouragement to people who want to kill the patent that comes out of that inventive community by looking to somebody who doesn't qualify as an inventor and say, well, you told him something, blah, blah, blah. That goes in and can come into the litigation environment.

It is a very strong pull. I mean, you have to appreciate that the setting you are dealing with is you are 15 years after the invention has been made. You are in litigation. It is a big drug. It is worth several hundred million dollars and the only thing that is protecting that drug is this one patent. And so there is a huge incentive to go in and talk to every single person and every institution that got involved before the patent application was filed, and that is an immense risk thrown into the equation of litigation. The comments that people are going to be making aren't written down. They are recollections. They are very difficult to characterize.

And I think that is the major risk that is being created by the current environment. If you take 102(f) out entirely from this type of an obviousness finding, you have extinguished that risk.

Mr. SMITH. Okay. Thank you, Mr. Kushan. I would like to ask you all one more question, but Mr. Steffe, do you have any quick comment to make, or is that——

Mr. STEFFE. Just in response to that, I think that by keeping it—it strikes a compromise by just allowing no prior art under 102(f) where it is from a co-inventor, because the main concern is that people aren't free to collaborate and form joint inventions without creating prior art against themselves, and this would provide incentive to be inclusive in naming inventors rather than providing

the temptation of forming a sort of secrecy agreement and then walking away and filing a minor modification.

Mr. SMITH. Okay. Thanks, Mr. Steffe.

Professor Thomas, you mentioned in your written testimony, you say, "It does not appear that the CREATE Act works toward international harmonization of the patent laws. Under European patent convention, subject matter derived from foreign oral disclosures counts as prior art while under the CREATE Act it may not. The CREATE Act may make innovators more willing to make use of discussions with their colleagues in future work. On the other hand, it may make innovators less willing to collaborate out of fear that others will modify their inventions and obtain patent protection on them. This concern is less stressing for domestic than foreign inventors," and so forth.

Let me ask Mr. Kushan to respond to that real quickly, and then Professor Thomas, as well.

Mr. KUSHAN. Thank you. To some extent, our patent system isn't designed——

Mr. SMITH. You will have to give me a quick response, since my time has expired.

Mr. KUSHAN. Okay. To some extent, our patent system isn't perfect. For some reason, we have decided to treat all that information outside of our borders as not important if it is not written down in a patent or a printed publication. I think a more coherent approach, if you want to address the harmonization question, is to make that information that is publicly known outside the United States have the same footing it has in the United States. So if it has the effect of being prior art, then fine, let us bring that in and let us harmonize. I think in this area, it is not—this isn't going to solve or get entwined in that problem.

Mr. SMITH. Okay. Thank you, Mr. Kushan.

By the way, I noticed that I am the first person to be subjected to the new blinking red lights, and so I will try to heed them.

The gentleman from California, Mr. Berman, is recognized for his questions.

Mr. BERMAN. Thank you, Mr. Chairman.

I was wondering if the other three panelists could respond to Professor Thomas's concern that this act will actually dissuade collaboration by making researchers worry that someone will take their research, make a minor change, and get a patent. Can you quantify whether that risk is greater or lower than the risk posed to the collaboration by the *OddzOn* case?

Mr. SODERSTROM. Speaking just from experience, I think that it is less. I think the *OddzOn* decision actually is the one that I fear the most, primarily because of the jeopardy it puts patents that are going to be subject to tremendous investment. Researchers, I don't need to tell anybody, are already under a lot of pressure to publish and to make things—to make their ideas public as much as possible. Stealing ideas probably happens, but I don't see it as a major concern. We have lots of remedies for that within the Patent Office already.

Mr. STEFFE. I would like to make a clarification about the *OddzOn* case. If I remember correctly, the *OddzOn* case involved a communication from a non-inventor and it was just a situation

that Professor Thomas was concerned about. The concern out there has been that the courts will take the *OddzOn* case and apply it to communications between future co-inventors and thereby frustrating collaborations between co-inventors. And so his concern is what actually occurred in the *OddzOn* case, but the concern has been applying that——

Mr. BERMAN. The communication from the non-inventor was used to defeat a patent?

Mr. STEFFE. Right, and that was the *OddzOn* case. And so I think that this legislation should definitely go forward, because I think it is better than what we have now. But again, I think there should be a minor tweaking.

Mr. KUSHAN. This is also an issue or a setting where you have to balance risks. I think the scenario that is being described is the inventor or the person who has information who enters into a collaboration not taking steps to protect his interest, and that is what, on one hand, you want to protect, you certainly don't want to have people taking advantage of others. But on the other hand, you have a lot of, and this is the far more frequent scenario, very healthy collaborations voluntarily entered into with all the protections defined by the parties and who gets to share the invention sales, et cetera, and in that scenario, you would want to encourage more of those collaborations.

I think the short answer is, the person who is sharing information under the new world you might create by the passage of the CREATE Act will take steps to protect their interests before they enter into collaboration, which is routinely done in the modern research environment. MTAs, contracts, things like that preserve all the respective interests of the parties who go into a collaboration, and I think that is far more easier to deal with and address than the world that we live under in the *OddzOn* scenario, where we entered into these contracts, we voluntarily communicate, everybody is getting their cut of the action, yet there is still a risk to the patent.

Mr. BERMAN. Let me just make sure I understand it in most simple terms here. Because of the *OddzOn* case, the threat now is that some initial, some comments in an initial collaborative effort will be used either by that person or by someone else to defeat a patent achieved as a result of this inter-institutional collaboration.

Mr. KUSHAN. Precisely.

Mr. BERMAN. And that if we fix that problem, the problem then becomes that somebody participating in this collaboration will now be able to sustain a patent which is just a minor variation of the original idea as discussed in the collaboration. Is that what we have on the one hand, on the other, and you think that the former problem is a greater one than the secondary problem?

Let me just ask my last question then to Dr. Soderstrom. To the extent that—I mean, your notion that the *OddzOn* case has negatively affected collaboration, that decision was decided in 1997 and you talk about statistics since 1998 that show that there is a great deal of collaboration, presumably inter-institutional, going on since that time. Is this a theoretical problem created by that decision which hasn't impacted on what's going on in the real world, or is

there some quantifiable evidence that people have been burned because of it?

Mr. SODERSTROM. No, it is clearly a real concern and we haven't been burned yet. We will be burned and it is just a matter of time. And when that happens, everything that we are threatening will occur.

Mr. BERMAN. There is a long tail for burning here.

Mr. SODERSTROM. Correct. It is around five to 7 years.

Mr. BERMAN. Okay.

Mr. SMITH. Thank you, Mr. Berman.

The gentleman from Virginia, Mr. Forbes, is recognized.

Mr. FORBES. Thank you, Mr. Chairman, and gentlemen, thank you for being here.

I would have to tell you that there is still a little bit of confusion up here as to exactly which direction we need to go, but I have a question for you. There is a survey conducted by the Association of University Technology Managers that revealed that universities filed 6,375 new patents in fiscal year 2000. In that same year, adjusted gross income received from licenses and options amounted to $1.26 billion. Without the passage of this legislation before us today, and I kind of follow up on what Congressman Berman said, what does the future hold, in your opinion, for research collaborations? How is it going to impact those dollar numbers?

Mr. SODERSTROM. I think we will have significant negative impact and the impact will be this. There will be a patent that will be subject to litigation and during the discovery, the evidence will be used under the *OddzOn* decision to defeat that patent and that will then make subject all other licenses from academic research institutions to pharmaceutical, biotech, high-technology companies subject to the same question. Every company will then back away and begin to decrease the amount of investment that they are willing to put into the commercialization of that technology.

Mr. FORBES. Is that your feeling, Mr. Kushan?

Mr. KUSHAN. Yes. I think you have to appreciate it from the corporate perspective. When you are offered a patent from a university for licensing, you are going to do some due diligence on that patent and you are going to review it. And every factor that is a negative factor—it is not a decision to just say "no" to the patent—it is going to decrease your valuation of that patent. So where there has been some pre-filing communication among different entities, we are going to put that in the negative factor—in the negative column, and we may say, give them less money under that license because we have got to take the risk that this patent is going to die once we go in to make a product in the market.

So these aren't binary decisions. They are steps down which will have the effect of decreasing the value that a company may put on a patent, that is the major effect that we are going to see over time. I think once the first big patent on a drug gets killed under this type of a scenario, then that is going to be a very prominent factor that weighs in the raw evaluation of university-sourced patents.

Mr. FORBES. Mr. Steffe, you had mentioned the fact that we needed some minor tweaking to 102(f). I don't know if you have had any discussions among the other panelists with what that tweaking should be, but if you could perhaps submit that language

to us. What is minor to one individual could be major to someone else and that information would be helpful to have at some point in time, as well.

Mr. STEFFE. Well, I think if it is just covered such that the communication between co-inventors is not prior art against future inventions, I think it would not have a negative impact on future collaborations because, for example, biotech companies are going to collaborate regardless of what the patent laws says because they can't afford not to collaborate. So they would prefer some certainty, legal certainties, so the lawyers aren't telling them, you have got to assign all your rights under collaboration to one entity at the outset because companies like to own their own patents, obviously.

So I think the proposed tweaking would just be seen as a compromise between avoiding the piracy problem while maintaining freedom for co-inventors to freely share ideas.

Mr. FORBES. Good. Thank you, Mr. Chairman.

Mr. SMITH. Thank you, Mr. Forbes.

The gentlewoman from California, Ms. Lofgren, is recognized.

Ms. LOFGREN. Thank you, Mr. Chairman. I think this is a very helpful hearing and very interesting. I think it is clear what we want to accomplish, but we don't want to create other issues that we haven't anticipated. So your testimony, each of you, is very helpful.

I am wondering, Mr. Kushan, what you think of Professor Thomas's suggestion to amend the CREATE Act to specify that 102(f) prior art may not be considered for purposes of non-obviousness only if that subject matter is prior art exclusively under 102(f). Do you think that that will help or not?

Mr. KUSHAN. That is, in my view, perfectly consistent with what the Act is trying to do. We are speaking of information that is not going to qualify under any other form of prior art definition. So it is, it is a very precise and helpful amendment.

Ms. LOFGREN. And I am wondering, Professor Thomas, if you have other suggestions for us to consider and for the witnesses to opine on relative to the concerns that you identified in your testimony.

Mr. THOMAS. Thank you. I certainly defer to my colleagues at the lab bench and in the courtroom over their sense of weights and balances between discouraging and disincenting innovation. What I would observe are a few things regarding the concerns that, 15 years down the road, a 102(f) defense will be made in court.

First, in my view, the courts are rather chary of "Johnny-come-lately" claims by putative disclosers that say, "15 years ago, I disclosed this." They are generally going to have to have very tight evidence of that.

And second, when they do have evidence of that, they are usually not trying to strike down the patent. They are trying to become joint inventors. In other words, they are not trying to get the patent struck down. They are trying to get a piece of the action for themselves because they are licensed, if that is the scenario, and we have seen a number of cases where a joint inventorship claim has been raised. But I have seen none under 102(f). So my guess is what we are really going to see are people not trying to get rid of the patent but trying to get a piece of it for themselves.

Ms. LOFGREN. But Professor, we are concerned not just about the outcome of the court ruling, but we wish also to discourage litigation, if that is at all—we don't want to create the burden of litigation needlessly if we can avoid that.

Mr. THOMAS. Right. The CREATE Act would not speak to joint inventorship claims as it is currently structured, so you would still have these claims of joint inventorship one way or the other.

Ms. LOFGREN. Mr. Kushan?

Mr. KUSHAN. I think it is also useful to look at the *OddzOn* decision. It is not very clear who the parties were in the *OddzOn* decision, but if you look at it carefully, the person who picked up this information and used it as a hammer on the patent doesn't appear to be the person who gave the information to the person who got the patent.

So it is not a setting—the scenario that we are envisioning is that somebody completely external to this relationship between the two collaborators is going to dig in and find this information and then use it to attack the patent. That is a risk factor that is very difficult to measure when you are looking at the patent because you have got to go depose all these people and find out what they thought of the invention and what they said.

It is fair to say maybe 15 years and maybe 5 years, but it is certainly not contemporaneous, and as we all learned in litigation, as time progresses, memory gets very fuzzy, especially when you see what you thought was your invention being sold for lots of money. And now all of a sudden, you see a very strong incentive to recreate history, which causes huge complications that you cannot predict.

Ms. LOFGREN. I think that it seems that we should seriously consider the Professor's suggestion about 102(f) as a narrowing amendment. Does anyone disagree with this suggestion? And I suppose if there are other specific details, we might want to take a look at those, too, but I think that might improve—I am a cosponsor of the bill and I am very happy to proceed with it. It looks like that might narrow this a little bit, Mr. Chairman, and I appreciate your yielding me time and yield back.

Mr. SMITH. Thank you, Ms. Lofgren.

The gentlewoman from Wisconsin, Ms. Baldwin, is recognized.

Ms. BALDWIN. Thank you, Mr. Chairman. I just want to appreciate the panel for your testimony today. Like other members of the panel, I have a district which has that great collaborative environment with a major research institution and many spin-off and not-spin-off of businesses.

But as comes with the relative lack of seniority, you have had a chance to comment on the case, the draft legislation, and react to one another's proposals for tweaking that legislation. There is not much ground we haven't covered, so I have no further questions other than to thank you for your testimony here today.

Mr. SMITH. Thank you, Ms. Baldwin.

It strikes me, given the technical nature of all of our questions, that this is a hearing probably only a lawyer could love, and not all lawyers would love this, which, Dr. Soderstrom, makes it all the more important that you were here to represent non-lawyers, I guess.

In any case, thank you all for your testimony. It has been very, very helpful. We will go forward and try to improve this legislation. I sense that Mr. Berman has a final question.

Mr. BERMAN. One question. The way this bill is written now, it has retroactive application. Does that mean it retroactively insulates all collaborations, inter-institutional collaborations from the effect of the *OddzOn* decision whether or not a patent has yet been filed, or does it—what is your interpretation of the effect of the retroactive application?

Mr. KUSHAN. From the way I read it, it would insulate patents from challenge where there has been no activity started to challenge a patent. So if the patent is in litigation and this is a live issue and then the law changes, the old law will govern the resolution of that fight.

The thing I find interesting about this setting is that no one knows about this information, so it is hard to rely on this secret information to make decisions about what you should do about a patent, and so it doesn't have the classical retroactive effect. This isn't public information out there that people are using to base their business decisions on.

Mr. BERMAN. But if the admitted, though less serious risk of passing this legislation is to allow this to insulate the person who gets the patent with some minor variation, and the goal of the legislation is to incentivize inter-institutional collaborations, why do you need a—why can't you avoid the potential for validating the patents that really were minor variations of previously received information and at the same time incentivize the collaborations by just having it apply from prospectively?

Mr. KUSHAN. I would invite our colleague from Yale to also dive into this, but we are talking about a lifespan in the patent where it has gotten birth at the time of invention. Then you have got your teens, which are going out and trying to be sold to become a commercially viable invention. There is a huge population of patents out there that are very early in their life and have not yet formed the basis of an interesting commercial potential. So I see this as being a way of encouraging the value and strengthening all those patents out there so that you increase the odds of commercialization. I think if you limit it to prospective——

Mr. BERMAN. Oh, the continuing collaborations that allow the commercialization of already-filed patents?

Mr. SODERSTROM. I think that the point that needs to be made, I think we make a simplification if we think that there is a patent that equates to a product. It oftentimes is a series of patents and those patents evolve over time. We sometimes call them improvements. Sometimes they are under the patent statute, but sometimes they are totally independent inventions which contribute to the commercialization of that particular area.

The reason I would become concerned that we don't have it retroactive is that we have so many of the technologies that are in the pipeline right now, where companies are making the investment, and if all they have to protect them at the end of the day is post-Act intellectual property, it may substantially weaken their resolve. As was pointed out earlier, these are extremely risky investments that the companies are making and we put that in jeopardy.

Mr. BERMAN. So it could turn off the investment faucet?

Mr. SODERSTROM. That is what I would fear might happen.

Mr. BERMAN. Thank you, Mr. Chairman.

Mr. SMITH. Thank you, Mr. Berman, and thank you all again for your testimony. Today has been very, very helpful, and we will, I am sure, be in touch in regard to the bill, as well. Thank you all.

We stand adjourned.

[Whereupon, at 11:05 a.m., the Subcommittee was adjourned.]

APPENDIX

MATERIAL SUBMITTED FOR THE HEARING RECORD

June 16, 2003

The Honorable Lamar Smith
Chairman
Subcommittee on Courts, The Internet
And Intellectual Property
House Committee on the Judiciary
B-351A Rayburn House Office Building
Washington, DC 20515

Dear Mr. Chairman:

On behalf of the Wisconsin Alumni Research Foundation ("WARF"), I write to thank you for introduction of H.R. 2391, the Cooperative Research and Technology Enhancement (CREATE) Act of 2003, and for holding a legislative hearing on the proposed legislation on June 10, 2003. WARF supports the proposed legislation, as introduced, or as modified to effectuate the policy purposes underlying the bill's introduction: that is, to promote collaborative research amongst and between the university and non-profit sector, the private sector, and government. I hereby request that this letter be made a part of the hearing record.

WARF is the patent management organization for the University of Wisconsin-Madison. Pursuant to agreements, WARF, through its non-profit subsidiary WiSys, also represents the patent interests of the entire University of Wisconsin system. The WARF mission, to support scientific research at the University of Wisconsin, is accomplished by transferring university technology to the marketplace for the benefit of the university, the inventors and the public. Licensing income is returned to the university to fund further scientific research.

Founded in 1925, WARF is one of the oldest organizations in the United States engaged in university technology transfer. Over its 78-year existence, WARF has not only protected the fruits of scientific research; it has actually contributed close to $700 million of licensing income to new UW-Madison scientific research. Of greater significance is the fact that WARF's technology transfer successes have had a profound and positive effect on the welfare, health, and safety of humankind. During the 107th Congress when I testified before this subcommittee during an oversight hearing on Patent Law and Non-Profit Research Collaboration, I described these successes. In my written statement for the Subcommittee (attached), I shared two significant accomplishments. First, Professor Hector DeLuca at the UW-Madison has numerous vitamin derivatives (protected by close to 200 U.S. patents) that are widely being used today to treat osteoporosis, renal disease, and other dreaded diseases. Second, Professor James Thompson's human embryonic stem cell lines have unprecedented potential for research and clinical application of presently untreatable diseases such as Parkinson's disease and diabetes. These stem cell lines are presently being shared with the public pursuant to regulations promulgated by the Bush Administration.

Permit me to add three current success stories at UW-Madison specifically in the area of collaborative research.

1. From the beginning and continuing to this day, MRI medical imaging technology represents a critically successful collaboration between the academic environment and private industry. GE Medical has engaged in active collaborations with a number of academic institutions, including Wisconsin and Stanford University. Without those collaborations, we would not have the imaging capabilities that we have today.
2. Digital subtraction angiography has allowed real-time visualization of coronary arteries to determine blockage. This technology is critical to modern cardiac patient care. First developed by Professor Charles Mistretta at Wisconsin, applied research and development by the private sector have made the technology clinically useful.
3. Automated PCR technology was developed by Cal Tech scientists (which included Lloyd Smith who is now at the UW-Madison). Without the automated PCR technology, the human genome could not have been sequenced in our lifetime.

The benefit to the public derived from these and other inventions is incalculable. Simply put, these scientific advances are saving lives.

Currently, large industry is getting out of the business of basic research. Research collaborations between academe and industry are consequently becoming more and more critical, not only for American pre-eminence but also for the public good. Key sectors – such as pharmaceuticals, biotechnology, and nanotechnology – will depend on these collaborations.

Despite success stories, identifiable problems exist. One of them is addressed by the CREATE Act. A decision by the U.S. Court of Appeals for the Federal Circuit (in *Oddzon Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396 (Fed. Cir. 1997)), threatens to chill collaborative and cooperative activities. Because the *Oddzon* decision allows a third party to challenge the validity of a patent achieved through a collaborative activity, it is a ticking time bomb. The Subcommittee previously amended the Patent Act in 1984 to encourage open communications among members of research teams working at universities, in corporations and other organizations. Pub. L. No. 98-622, 98th Cong., 2nd Sess. (1984), 98 Stat. 3383. The *Oddzon* court held that the 1998 amendments applied to collaborations within organizations. The CREATE Act takes the necessary step of promoting cooperation between organizations. In light of the fact that other sections in the patent law encourage collaborations between and amongst universities, the government and the private sector, *see* Chapter 18 (the Bayh-Dole Act), the CREATE Act is on firm policy ground. The solution is a legislative one. Indeed, the *Oddzon* court invited congressional intervention.

In conclusion, WARF supports the CREATE Act because it:

- Promotes collaborative research amongst and between the university and non-profit sector, the private sector and the government to achieve the promise of the 1984 amendments;
- Reverses the holding in the *Oddzon* case; and
- Preserves the protection of Chapter 18 of the Patent Act from amendments.

Mr. Chairman, WARF looks forward to working with the Subcommittee on this important legislative endeavor. I commend you for your leadership and thank the impressive array of subcommittee members who have decided to cosponsor the CREATE Act.

Sincerely,

Carl E. Gulbrandsen
Managing Director
Wisconsin Alumni Research Foundation

ATTACHMENT

PREPARED STATEMENT OF CARL E. GULBRANDSEN

HEARING OF THE SUBCOMMITTEE ON COURTS, THE INTERNET, AND INTELLECTUAL PROPERTY

MARCH 14, 2002

Mr. Chairman, thank you for the opportunity to testify before your Subcommittee on the important topic of "patent law and non-profit research collaboration."

My name is Carl E. Gulbrandsen. I am the Managing Director of the Wisconsin Alumni Research Foundation, known as WARF. WARF is the patent management organization for the University of Wisconsin-Madison. My statement today is being made on behalf of WARF and the Council on Governmental Relations known as COGR. COGR is an association of 145 research-intensive universities in the United States. They promote policies and practices in research administration that balance accountability and recognition of the interests of all parties in achieving the maximum scientific benefit from both federal and institutional investments in research. Neither WARF nor COGR have received any federal grants, or engaged in any federal contracts or subcontracts that require reporting under House rules.

I. BACKGROUND

WARF was founded in 1925 and is one of the earliest organizations engaged in university technology transfer. WARF exists to support scientific research at the University of Wisconsin-Madison. This mission is carried out by transferring university technology to the marketplace for the benefit of the university, the inventors and the public. Licensing income is returned to the university to fund further scientific research.

Over its 76-year existence, WARF has contributed over $600 million of licensing income to UW-Madison scientific research; but of greater significance is the fact that WARF's technology transfer successes have had a profound and positive effect upon the welfare, health and safety of humankind. Included among university inventions patented and licensed by WARF are: Professor Harry Steenbock's Vitamin-D invention which essentially eradicated rickets as a childhood disease; Professor Karl Elvehjem's copper-iron complexes which improved the physiological assimilation of iron in humans; Professor Karl-Paul Link's discovery of Coumadin(r), the most widely used blood-thinner for treatment of cardiovascular disease, and its counterpart Warfarin, still the most widely used rodenticide world-wide; Professor Charles Mistretta's digital vascular imaging technology which enabled accurate diagnosis of blockage of the vessels of the heart; Professor Hector DeLuca's Vitamin-D derivatives which are widely used to treat osteoporosis, renal disease and other diseases; and currently, Professor James Thompson's human embryonic stem cell lines which have unprecedented potential for research and clinical application of presently untreatable diseases such as Parkinson's disease and diabetes. In total, the benefit to the public derived from these and other inventions is incalculable.

The success of bringing these and countless university inventions to the marketplace has depended on rich collaborations among scientists within the university; collaborations among scientists at different universities and collaborations among university and industry scientists. Collaboration among scientists in husbanding research dollars makes good sense with the cost and complexity of research today especially with various institutions engaged in essentially the same technological areas. Moreover, the evolution of science has made interdisciplinary research more and more common and, in fact essential, if solutions to complex problems are to be found. A very recent stunning example of this is the sequencing of the human genome.

Collaborative research among, private, public and non-profit entities is quantifiably important to the U.S. economy. In 2000, non-profits and universities spent a record $28.1 billion on research and development much of which involved collaborations among private, public and non-profit entities. The positive effects of these collaborations on the U.S. economy are substantial. For example, in 2000, sales from products developed from inventions that were transferred from university research centers resulted in revenues of about $42 billion,[1] and U.S. universities, hospitals

[1] Calculated on the realized gross license income applying an average of 3% as the royalty charge.

and research institutes realized almost $1.2 billion in gross license income much of which was used to fund additional research.[2]

Public funding of university research and the encouragement of collaborations among scientists at public, private and non-profit entities has been a keystone of the United States strength and leadership in high technology and biotechnology. With the bulk of university research being supported through federal grants and contracts, to be prudent with the taxpayer's money, it again makes good policy sense to encourage collaboration among scientists for the public interest. And actually, there has been an increase in the number of collaborations. Today WARF has over 70 inter-institutional agreements reflecting such collaborations. In these inter-institutional agreements, there is joint ownership of the results of the research by the collaborating scientists since most institutions operate under the provisions of law that give the institution the right to retain title to any invention made with federal funds. That is the applicable rule even where the institution is in a sub-contracting situation where the prime contractor is the recipient of federal funds. Thus, in collaboration on an invention, each party may hold ownership rights.

II. UNIVERSITY PATENT LICENSING

University patent licensing as we know it today has its roots in enactment in 1980 of Pub. L. No. 96–517, the Patent and Trademark Law Amendments Act, and amendments included in Pub. L. No. 98–628, enacted into law in 1984. *See* 35 U.S.C. §§ 200–212. This Subcommittee played an instrumental role in the crafting of a chapter of the Patent Act relating to patent rights in inventions made with federal assistance (chapter 18) (referred to as the Bayh-Dole Act), and its cardinal principle that the public benefits from a policy that permits universities and small businesses to elect ownership of inventions made under federal funding and to become participants in the commercialization process. After 1984, universities and colleges developed and strengthened the internal expertise needed to engage effectively in the patenting and licensing of inventions. A measure of the success of Bayh-Dole Act is the growth of the Association of University Technology Managers ("AUTM") from 113 members in 1979 to over 1800 today. The Act, so successful in the transfer of university technology to industry, encourages collaborations between industry and university scientists. It is well known that industry depends heavily on collaborations with universities for basic research. In the pharmaceutical, biotech and hi-technology areas, America's universities are the engines of cutting-edge ideas that have kept this country's industries the world leader in new technology. These collaborations between scientists at separate universities and between industrial and university scientists often result in joint inventions.

III. A THREAT TO COLLABORATIVE RESEARCH

In spite of the trend toward scientific collaboration and the economic and practical necessity for such collaborations, a recent decision of the U.S. Court of Appeals for the Federal Circuit threatens to chill such collaborative activity. This decision, which cries for correction, is *Oddzon Products, Inc. v. Just Toys, Inc.*[3]. Oddzon interpreted subsection 103(c) of the Patent Act to hold that prior art under subsections 102 (f) and (g)[4] could be used to determine the obviousness of an invention where:

a. there was no common ownership or assignment of the invention and information being shared among collaborators; and

b. the information exchanged was not publicly known.

That holding made it clear that information under 102 (f) or (g) could invalidate a patent in the circumstances of joint collaborative research. The *Oddzon* decision has been viewed as creating a significant threat for the loss of intellectual property rights for inventors who engage in joint research and development projects with scientists not employed by the same entity, be it a university or corporation. Thus, while the need for collaborative research in the public interest is becoming more and more evident, the *Oddzon* decision exerts a substantial chilling effect on collaborative efforts among universities, the private sector and the government.

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[2] Citing AUTM Licensing Survey 2000, Association of University Technology Managers, Inc., Norwalk, CN (2000).

[3] 122 F.3d 1396, 43 U.S. P.Q. 2d 1641 (Fed. Cir. 1997).

[4] Section 103(c) was amended by the American Inventors Protection Act of 1999 to add Section (e) to the 103(c) exclusions.

This is clearly not what Congress, and this Subcommittee, intended when it amended section 103(c) in 1984 in the Patent Law Amendments Act of 1984[5] in order to encourage open communication among members of research teams working in corporations, universities or other organizations. *See* Remarks of Robert W. Kastenmeier, 129 Cong. Rec. E5777 (daily ed., Nov. 18, 1983). It was considered at that time important to the economic interests of our country to encourage collaborative research. This provision of the patent law was particularly important for large corporations that rely on open communication and collaboration among various research teams within the corporation and has succeeded in encouraging free communication among the employees of large corporations and within universities.

A bit of legislative and judicial background is in order. The current quandary regarding section 103 had its roots in a decision of the caselaw of the U.S. Court of Customs and Patent Appeals, the forerunner of the Federal Circuit, which interpreted section 103 to mean that earlier inventions made by individual members of a research team would be used under section 103 to preclude the team's invention from being patented.[6] This caselaw was a significant concern to entities, both public and private, that utilize team research. Seeking reform, they approached this Subcommittee. And the Subcommittee responded, producing a legislative proposal that was enacted into law. *See* P.L. No. 98–622, 98th Cong., 2d Sess. (1984), 98 Stat. 3383. Section 103 was amended by adding the current subsection 103(c) to address the problem created by the CCPA's interpretation related to team research *within* an organization. The legislative history of the 1984 amendment clearly establishes that subsection 103(c) was designed to help encourage teamwork at least within organizations. Given the text of subsection 103(c) and its legislative history, it is clear that the enactment of subsection 103(c) sought to encourage teamwork among researchers, rather than stifle team research. In floor debate, Rep. Kastenmeier (who served as floor manager) characterized the amendment as being broader than teamwork "within" organizations, stating that the "change will be of material benefit to university and corporate research laboratories where the free exchange of ideas and concepts may have been hampered by the current state of the law with respect to what constitutes 'prior art.'" *See* 130 Cong. Rec. H10522, 10529 (daily ed. , Oct. 1, 1984), section-by-section analysis inserted in the record by Rep. Kastenmeier. Thus, it can safely be assumed that certain inter-organizational exchanges were not expressly exempted because there was a different research paradigm in place at the time of enactment.

However, after the passage of thirteen years, the *Oddzon* court held that prior art under sections 102(f) or (g) could be used to determine the obviousness of an invention in situations where (a) there was no common ownership or assignment of the invention and information being shared among the collaborators, and (b) the information exchanged was not publicly known. Effectively, the *Oddzon* decision creates a significant threat for the loss of intellectual property rights for inventors that engage in joint research projects with scientist from a different company or institution.

The solution is a legislative one. The *Oddzon* court itself invited Congress to review its decision stating that "it is sometimes more important that a close question be settled one way or another than which way it is settled. We settle the issue here (subject of course to any late intervention by Congress . . .)." 122 F.3d at 1403.

Government-led initiatives to encourage the unhindered flow of information among scientists in the interest of meeting the technological needs of the country and maintain its technological leadership in the world are key elements in the consideration of the present initiative to recognize the adverse impact that the *Oddzon* decision is having on those broad goals. More immediate to the university sector is the potential loss of invaluable intellectual property rights and the delays or failure to achieve research goals where a collaborative effort would offer an opportunity to efficaciously move ahead.

Chapter 18 of the Patent Act is of great value for universities as it provides retention of title of their intellectual property. Universities are also keenly aware of its objective, which is to utilize the patent system to transfer technology to the private sector for development of the technology in the marketplace. The private sector is fully aware of the Chapter 18 having interfaced with it for over 20 years, and appreciates that it affords a basis for protecting marketplace development and investment efforts. A significant factor in that university-private sector relationship is the willingness and opportunity to define ownership of an invention made jointly by those entities and the disposition of such jointly-owned inventions should the need arise. That opportunity under the proposed legislation should lay to rest voiced concerns about two patents directed to the same subject matter issuing to different parties

[5] P.L. No. 98–622, 98th Cong., 2nd Sess. (1984), 98 Stat 3383

[6] *See In re Bass*, 474 F.2d 1276 (CCPA 1973) and *In re Clemens*, 622 F.2d 1029 (CCPA 1980).

in the event a collaborative arrangement is dissolved and afford a further spur to greater collaboration between the university and private sectors. This could readily result in more efficient development of products utilizing tax supported research results, and an increase in the transfer of technology for the public good.

Towards this end, we would propose a clarifying amendment to section 103 (c) that would result in:

- increasing the flow of information among scientists at different institutions;
- increasing the collaboration of scientists both within and without a given institution;
- promoting collaborations between the university and the private sector;
- promoting collaborations between government laboratories and the private sector as well as with the university sector; and
- enhancing the national pool of knowledge because of the greater unhindered flow of information among scientists.

The proposed amendment should be prospective only. Further, the amendment should not affect any final decision of a court or the Patent & Trademark Office that is rendered prior to the date of enactment and, should not affect the right of any party in any case pending before the PTO or a court on the date of enactment to have rights determined on the basis of the substantive law prior to the date of enactment.

IV. RELATED ISSUES

There is widespread recognition that the Bayh-Dole Act has been and continues to be successful beyond all expectations. It is unique in the world and is an essential component in the United States' global leadership in technology. At WARF, we receive numerous visitors each year from around the world. Invariably, our foreign visitors ask about statutory provisions in the patent law relating to patent rights in inventions made with federal assistance and express the wish that their own countries would adopt such forward-thinking legislation. This committee can be justifiably proud of the role it played in passing such a successful, landmark piece of legislation.

Yet, in spite of its undisputed success, there are continued attempts to alter the statutory framework so as to favor certain industries or groups. I trust that this Committee in its wisdom will safeguard such an important legacy of this committee and oppose any legislation that compromises its demonstrated success.

V. CONCLUSION

Mr. Chairman, thank you again for your time and attention. In conclusion, I leave you with three recommendations:

- an amendment to the Patent Act is necessary to promote collaborative research amongst the university and non-profit sector, the private sector and the government to achieve the promise of the 1984 amendments of this Subcommittee;
- an amendment which will, prospectively, reverse the holding in the Oddzon decision; and
- protection of Chapter 18 of the Patent Act from amendments that compromise its demonstrated success.

If there are any questions, I will be pleased to answer them.