## Testimony of

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Intellectual Property

Hearing on H.R. 1908, "The Patent Reform Act of 2007"

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#### STATEMENT

Good afternoon, Chairman Berman, Ranking Member Coble and members of the Subcommittee. My name is William (Bill) Tucker and I serve as the Executive Director for Research Administration and Technology Transfer in the University of California's Office of the President. I am here to testify on behalf of the University of California. Thank you for the opportunity to appear before you today to discuss the very important issue of patent law reform and specifically to offer our preliminary analysis of H.R. 1908, the 'Patent Reform Act of 2007.' The University of California (UC) appreciates the leadership of the House Judiciary Committee on the issue of Patent Reform, particularly in examining improvements that would best serve the nation's continued success at developing inventions that benefit the American public. UC looks forward to working with the Committee as it considers patent reform legislation.

My career has spanned both the academic and industrial sectors, starting with a postdoctoral research fellowship at Stanford University under Professor Stanley Cohen, one of the inventors of gene splicing methods that launched the biotechnology industry, then as part of one of the first companies to explore opportunities for commercial applications of genetic engineering to agriculture. After working as a bench scientist during which time I was an inventor on two issued patents, I moved into technology management and business development working at various technology-based companies before joining UCs Office of Technology Transfer, where I focused on licensing plant varieties bred by UC faculty. I am now the Executive Director overseeing the administration, coordination, and support of technology licensing activities throughout

the UC system. My experiences within both academia and industry have helped me appreciate the power of the U.S. patent system as a catalyst for creating technological change and economic value.

I should mention that UC is a member of several higher education associations such as the Association of American Universities (AAU), the American Council on Education (ACE), the Association of American Medical Colleges (AAMC), the Council on Government Relations (COGR) and the National Association of State Universities and Land Grant Colleges (NASULGC), all of which have been actively reviewing patent reform legislation on behalf of universities. UC concurs with these organizations' recent joint statement on S. 3818, the 'Patent Reform Act of 2006,' which was submitted to the House and Senate Judiciary Committees. To the extent that the provisions of H.R. 1908 are similar to the provisions in S. 3818, the comments offered today by UC are in large measure reflective of the higher education associations' statement.

In view of the short time frame between the introduction of H.R. 1908 last week and today's hearing, UC understands that the higher education associations as well as individual universities will need to undertake a more thorough review of H.R. 1908 before reaching any final position on the legislation. My comments today on behalf of UC are preliminary; we are continuing our review of the legislation.

In evaluating H.R. 1908, UCs perspective is informed by its position in the patent community as a leader in technology transfer between academia and private industry, serving companies ranging from start-up ventures to Fortune 500 companies, and across all the industry groups who benefit from the innovative work done throughout our university system. It has been UCs experience that the U.S. patent system has worked

well to foster innovation and to allow University-developed inventions to reach the marketplace for the benefit of the public.

UC supports many of the patent reform proposals in H.R. 1908, but is also concerned with changes to the U.S. patent system which could weaken the ability of patent holders to protect the rights to their inventions, or which could harm university technology transfer efforts.

#### I. Background About UC's Technology Transfer Program

UC is comprised of ten campuses, including five medical schools, and participates in the management of three national laboratories, with over 170,000 faculty and staff serving 200,000 undergraduate and graduate students. Our many scientists and engineers conduct basic and applied research, collaborate with other research partners to build on the nation's scientific knowledge base, educate and train students at all levels, and make discoveries that can be transferred to industry and translated into products that benefit the general public. UCs technology transfer program is at the heart of this transition from promising early stage research to products and applications that benefits the public.

UC established its first technology transfer office in the 1970's and since then has played an instrumental role in growing the California and national economy by leveraging the U.S. patent system to transform the technologies created by our faculty and staff into patented technologies that become the basis for new companies and industries. UC technology transfer encompasses a range of activities carried on throughout the system to facilitate this commercialization, including not only through traditional patenting and licensing efforts, but also through the development of relationships with businesses, industry, and government, in order to enhance the research

and education missions of UC and contribute to the economic prosperity of California and the nation.

For twelve consecutive years, UC has led the nation in the number of patents issued by the U.S. Patent and Trademark Office (USPTO) to universities, receiving 390 patents during 2005 alone (the latest date for which we have information). Indeed, in the recent Milken Institute report "Mind to Market: A Global Analysis of University Biotechnology Transfer and Commercialization," UC was listed as one of the top universities in the world for successful technology transfer efforts. UC expends more than \$4 billion on research activities, two-thirds of which comes from the federal government through contracts and grants. UC faculty disclosed a total of 1,314 inventions to UC in 2005. Since the inception of UCs technology transfer program, over 700 inventions have been translated into products with many more in the pipeline, and the ensuing royalties have been distributed to investors and the campuses to be reinvested in education and research. The American public reaps the benefits of the federal investment when products reach the marketplace for general use.

UCs technology transfer successes contribute to important advances in scientific research and have a significant impact on the quality of lives of people in the U.S. and worldwide. Among UCs inventions that have been successfully commercialized are:

- a vaccination for the potentially-fatal Hepatitis B disease;
- the Cohen-Boyer recombinant DNA patent held jointly by UC and Stanford University that helped to spawn the development of the biotechnology industry;
- lung treatments for respiratory problems associated with premature births;

- a laser/water Atomic Force Microscope that helps scientists to better view and analyze different properties of matter at the nanoscale;
- a dynamic skin cooling device that allows more effective laser surgery with less pain and less post-operative scarring;
- the minimally invasive Guglielmi Detachable Coil used to treat brain aneurysms;
- the Cochlear Ear Implant to assist those with hearing loss;
- glucose monitoring techniques useful for diabetics; and

• the Nicotine Patch that assists smoking cessation, among many others. Inventions developed at UC and other U.S. universities have provided significant benefit to society, improving the health of people throughout the world. Some of these discoveries from universities are highlighted in a recent report from the Association of University Technology Managers (AUTM), the "Better World Project," which is available at: <u>http://www.betterworldproject.net/</u>.

A university's ability to ensure that these technologies are successfully translated into useable products is predicated on having strong, reliable patents that encourage industrial partners and private equity funding sources to invest resources and commit to moving a laboratory-based discovery through the arduous and often risky development and commercialization process. Having a strong U.S. patent system where patent holders can depend on the certainty of their patents helps to ensure that technology transfer can occur.

#### **II.** University Patent Licensing

#### A. The Bayh-Dole Act and University Technology Transfer

To understand UCs view of patent reform legislation, some background on university patent licensing is helpful. Before 1980, approximately 25 universities across the nation had established technology transfer offices. These offices were granted only a handful of patents and the ability to assert title to these patents was hampered by the uncertainty surrounding the timing and scope of agency approvals. There was no uniform federal patent policy at the time. In addition, universities were forced to file patent applications before their value could be assessed, and before they knew if they would be permitted to own the patent at all. Companies were disinclined to license these technologies given their uncertain legal status, and as a result, many potentiallypromising inventions were left to languish.

Today, more than 230 U.S. universities have technology transfer offices, evidence of the success of the groundbreaking Patent and Trademark Amendments Act, commonly known as the 'Bayh-Dole Act,' legislation passed in 1980 under the leadership of the House Judiciary Committee and the House Science Committee. The 'Bayh-Dole Act' allows universities to retain title to patents made under federal funding in exchange for their commitment to work diligently with private industry to develop those inventions into useful products for the U.S. economy. The Bayh-Dole Act has been called one of the most successful pieces of legislation of the twentieth century and has been instrumental in furthering universities' paramount goal of creating and disseminating knowledge in an open academic environment while ensuring that the benefits of that research can be shared by the public.

UC appreciates the Committee's continued commitment to preserving the Bayh-Dole Act with the Sense of Congress Resolution to honor the 25<sup>th</sup> Anniversary of the Bayh-Dole Act, which passed in the House of Representatives on December 6, 2006.

#### B. Small Businesses Need Strong Patents to Thrive in the U.S. Economy

Universities are engines for innovation, but must rely on industrial partners to bring early stage ideas to the marketplace. As this Committee considers patent reform legislation, it is critically important to consider the implications such legislation will have on start up companies, other small businesses and the nation's economy. In particular, startup companies depend on strong patent protection to attract the venture capital and other financing necessary to launch a new enterprise.

As encouraged by the Bayh-Dole Act, UC honors a preference to license its federally-funded inventions to small businesses. For example, in 2005, UC ranked second only to MIT in the number of licenses entered into with new startup companies during 2003-2005, as reported by the AUTM U.S. Licensing Survey (<u>http://www.autm.net/surveys/dsp.Detail.cfm?pid=194</u>). UCs licensed technologies can be linked to approximately 300 existing startup companies which use technology ranging from medical compounds and devices to electronics to biotechnology to semiconductors/nanotechnology. (See Figure 1.)

Over the past 20 years, on average over 80 percent of companies founded based on a license to UC technologies are still in operation, either as stand-alone entities or through merger and acquisition. This observation is not unique to UC, but common among university based startups. These resilient university-based startup companies create long-term jobs and lead to sustainable regional economies. (See Figure 2.)

Such an innovation ecosystem, in which the universities, inventors, entrepreneurs and investors interact, has the potential to reinvent local economies. By way of example, such an innovation ecosystem helped the San Diego economy transition to one of the nation's leading high tech and biotechnology centers after the downsizing of the U.S. military presence there.

The types of relationships and the stimulation of the regional economy exemplified by San Diego's example are replicated throughout the nation with many other universities. University research and licensing programs touch various aspects of the economy and it is extremely important that universities continue to play an instrumental role in supporting and growing the economy, creating jobs, encouraging American ingenuity and entrepreneurship, and making discoveries that are transferable to companies that are able to translate them into useful products.

#### III. UC Preliminary Analysis of H.R. 1908, the "Patent Reform Act of 2007"

UC applauds Chairman Berman, Ranking Member Coble and all of the Members of the Committee for their leadership on intellectual property matters, their stewardship of the intellectual property system and their care and concern for ensuring that the U.S. patent system is updated and performs well.

UC understands there are challenges with the current U.S. patent system and appreciates that patent reform legislation is intended to correct some of these difficulties, especially as they relate to patent quality and patent validity. In making changes to the U.S. patent system, however, UC urges the Committee to pay careful attention to the

unintended consequences that could negatively impact the technology transfer efforts of universities.

In moving toward a more robust patent system, it is critical for Congress to ensure that the U.S. Patent and Trademark Office (USPTO) will have the sustained and sufficient fiscal resources to allow the USPTO to continue to provide timely and high quality service to American innovators while implementing any changes resulting from the legislation. It is also important to consider whether any reforms will add additional burdens to the USPTO's workload that would lead to delays in the already lengthy patent pendency process. The escalating workload at the USPTO demonstrates the high rate of American innovation and inventiveness. However, the USPTO has been challenged both financially and administratively, resulting in increased pendency of applications and perceived lapses in the quality of examination.

#### A. UC Supports Many of the Proposed Reforms in H.R. 1908

Upon an initial review of H.R. 1908, UC supports many provisions, including:

- the proposed new derivation proceedings to determine appropriate inventorship in proceedings before the USPTO;
- the creation of a procedure for third parties to submit prior art to the USPTO concerning pending patent applications;
- changes to the patent venue and jurisdiction procedure statutes;
- the creation of a Patent Trial and Appeal Board;
- a review of the existing reexamination procedure to determine its effectiveness;
- some of the language to create a new Post Grant Opposition procedure;

- the retention of the 'best mode' requirement;
- that the legislation does not change the current state of the law on patent unenforceability;
- the retention of the CREATE Act, an important bill which encourages research collaborations in academic settings; and
- the retention of many provisions of the current prior art rules.

Many of these provisions of H.R. 1908 will help to encourage the issuance of stronger and better quality patents from the USPTO.

UC also wishes to thank the drafters for not including:

- a'loser pays'attorneys fee system for patent cases which had been included in S. 3818;
- language to repeal 35 U.S.C. § 271(f); or
- additional restrictions on injunctions or the filing of continuation applications.

UC would also have supported the inclusion of several additional provisions in H.R. 1908, including:

- a requirement that all patent applications be published after 18 months of their filing with the USPTO, and
- language to change the inequitable conduct defense so that findings are made by a court and only on appropriately-limited grounds of truly severe misconduct before the USPTO.

While UC supports many elements of H.R. 1908 as outlined above, UC remains concerned about certain other elements of H.R. 1908 as currently drafted.

### **B.** The Impact of the First-Inventor-To-File Proposal on University Technology Transfer Programs (Section 3)

H.R. 1908 would require the U.S. to shift its patent system to award patents not to the first person to invent a new invention, but rather, to the first person who filed a patent application with the USPTO for that invention. This is unprecedented in American history, though consistent with patent law in Europe and Asia.

UC believes that the strength of the U.S. patent system has in large part been the result of the existing patent rules, including the current first-to-invent system. In reviewing the situation, it is not unreasonable to posit that the first-to-invent system, with its public policy intent to reward innovation, collaboration and public discourse, is at least partly responsible for the historical strength of the U.S. commitment to the individual inventor.

UC is continuing to review the first-inventor-to-file system. However, we are in agreement with the points made in the statement of the higher education associations on S. 3818, that encouraged the Committee to ensure that any first-inventor-to-file system includes an effective grace period, a robust provisional patent application procedure, and a strong Inventor's Oath requirement.

## 1. The First-Inventor-To-File System Proposed by H.R. 1908 Is Likely To Heavily Burden Academic Licensors and Researchers

UCs primary concern with the proposed first-inventor-to-file system is that it will reward with a patent the person who has the means and ability to file patent applications as quickly as possible over the first person to conceive a groundbreaking idea and realize it in a working invention. UC strongly believes that this is likely to have a profound adverse impact on university technology transfer offices.

Under the current first-to-invent system, researchers at American universities have had the ability to develop their ideas, and have a one year grace period to get to the USPTO to file a patent application after disclosing their idea. This one-year grace period has allowed universities the time to evaluate the commercial potential and patentability of an invention and allowed universities to focus on locating the best licensing partner to develop the technology.

In a first-inventor-to-file system, inventors would not have rights to their inventions until they file a patent application with the USPTO before another party filed. There would be no one year grace period available with regard to third party publications and past patent filings. The result may be that university researchers lose their ability to obtain patents for inventions. In a first-inventor-to-file system, universities would have to act quickly to file applications in order to preserve their inventors' rights, often before conducting a reasoned analysis of the merits of an invention. Unless a quick filing occurs, a university could risk losing rights to those inventions altogether. And because research universities like UC receive such a large number of inventor disclosures in a wide variety of fields, this would be a huge burden for universities to undertake.

The first-inventor-to-file system may also create an incentive for others to profit at the expense of universities. Because university researchers typically publish the results of their research as soon as possible, others could theoretically review publications, speed up their own efforts to develop similar technology based on the ideas generated by research institutions, and then file with the USPTO as the first inventor to file. This situation is at odds with the university's goals of creating an open academic environment, which emphasizes the publication of research results in journal articles and the sharing of

information with scientific colleagues. To date, universities have been able to do so without the fear of losing the right to protect an invention if the invention is not first registered and filed with the USPTO before it is disclosed to anyone else.

It has been UCs experience that the interference proceeding available under current law has provided an important safeguard to ensure that only a true inventor gains patent rights. The interference procedure would be repealed by H.R. 1908. UC suggests that any patent reform legislation continues to provide a strong mechanism to allow true inventors to challenge an earlier filing by another party. The new derivative procedure created by H.R. 1908 may help to fill such a void.

## C. The Potential Problems For Academia Created by a First-Inventor-to-File System May Be Compounded by the "Absolute Novelty" Requirements and Lack of Broad One Year Grace Period in H.R. 1908 (Section 3)

UC thanks the Committee for including some form of grace period in H.R. 1908, under the proposed first-inventor-to-file system. While we are carefully evaluating the new language, we are concerned that it may be insufficient to effectively replace the protections of the one year grace period available under current law.

#### 1. "Absolute Novelty" May Impair the Public Disclosure of Inventions

As discussed previously, public disclosure and collaboration are crucial in the academic setting, where, unlike in the private sector, the emphasis is on publishing and sharing research results to advance the science rather than keeping new developments secret until patent applications can be filed. As UC interprets the legislation, under the 'absolute novelty' proposal, if anyone other than the inventor discusses the proposal in public before a patent application is filed, the inventor would lose the right to obtain a

patent on the invention because the public disclosures of any party other than the inventor would be considered prior art.

The removal of the current one-year grace period in conjunction with the firstinventor-to-file system will essentially force universities to either move immediately to file patent applications before a researcher's articles can be published or even discussed in public (causing potential delay to the researcher's work as a result), or to simply risk losing the right to patent the invention at all. While private companies can bind their employees to confidentiality agreement to avoid this risk, such an arrangement would be unacceptable to researchers working in academia, and thus places them at a disadvantage in terms of the potential commercialization of their work.

Rather than remove the current grace period, UC recommends that Congress retain the current grace period law and encourage other countries to adopt a similar grace period in their patent systems, consistent with the recommendation included in the National Academies' National Research Council report, a'Patent System for the 21<sup>st</sup> Century."

While UC has not taken a final position on switching to a first-inventor-to-file system, UC has concerns and is not certain that the benefits of switching to a first-inventor-to-file system would outweigh the potential negative consequences.

## **D.** The Patent System Must Be Supported by a Strong Inventor's Oath Requirement (Section 4)

UC is in agreement with the higher education associations' statement on S. 3818 which asks for a strong inventor's oath requirement to be included in any patent reform bill. At the heart of the U.S. patent system historically is the certainty that the named inventor is the one that truly made the invention, not someone who has learned of it from

someone else. An oath requirement also favors the independent inventor and the open environment of universities by encouraging honesty and full disclosure in the patent process.

A first-inventor-to-file system should be contingent on the law's continued requirement for a strong and mandatory inventor oath, to ensure that inventors are encouraged to disclose the full extent of their inventions to the public and that they are bound by the statements they have made.

However, as currently drafted, H.R. 1908 would permit a would-be inventor to avoid the requirement of attesting under oath that they truly invented the invention in question by submitting a"substitute statement" instead, which does not need to be made under oath. This further endangers inventors' rights. UC looks forward to working with the Committee to strengthen the inventor's oath requirement.

## E. Courts Should Be Given Discretion to Determine the Apportionment of Damages in Litigation (Section 5)

UC is in agreement with the higher education associations' statement on S. 3818 which suggested that trial judges already have ample discretion under *Georgia-Pacific* and the current case law to assess the relative economic value of a patented technology in determining damages for patent infringement, and thus does not believe that any statutory language is necessary to codify the apportionment of damages available for infringement. Since damages calculations in particular must be based on the circumstances between the parties in the lawsuit and the marketplace in which they operate, UC believes it would be best to continue to allow judges and/or juries to make these determinations on a case-bycase basis instead of introducing a new process for calculating the apportionment of damages.

## F. UC is Concerned that the Prior User Rights Expansion in H.R. 1908 May Be Too Vague (Section 5)

Under current law, "prior user rights" provides a limited defense from infringement for a party who actually "commercially uses" a patented technology before a patent application is filed by another party. By contrast, Section 5(d) in H.R. 1908 would significantly expand the "prior user rights" defense to include "*substantial preparations* for commercial use" of an invention, prior to the filing of a patent application. UC, consistent with the higher education associations' statement on S. 3818, opposes the expansion of "prior user rights" included in H.R. 1908.

## G. UC Believes One Post-Grant Cancellation Procedure is Sufficient (Section 6)

## **1.** UC is Concerned that the Two Additional Windows of Post-Grant Review May Lead to Gamesmanship

H.R. 1908 sets forth three "post-grant review" procedures, known as "cancellations," by which a petitioner can move to cancel a patent after it has been issued:

within 12 months of the patent's issuance (the 'first window'),
upon a showing of 'substantial economic harm' caused by the patent, at any time (the 'second window'), and

3) upon the receipt of notice of a possible claim of patent infringement under the patent (the 'third window').

While UC, consistent with the higher education associations' statement, supports the 'first window' of post-grant review, UC opposes the 'second' and 'third' window proposals as potentially burdensome to legitimate patent holders seeking to enforce their legitimate rights.

As currently drafted, the open-ended nature of the "substantial economic harm" opening of the "second window" may lead to strategic challenges to legitimate patents by free-riding competitors in an attempt to hamper a patent holder's ability to ascertain certainty that their patents are valid. This would be especially problematic for patent holders with limited resources. It could also lead to gamesmanship by parties with no real concern about the patent's validity but rather, simply wishing to impede the true inventors ability to enforce that patent against them. In addition, because the patent grant of exclusivity is only for a limited amount of time, abuse of the "second window" process would hamper the value of legitimately-obtained patents in the marketplace.

All of these concerns loom even larger in the new"third window" cancellation proposed in H.R. 1908. As a matter of practice, UC only notifies parties of infringement or files patent litigation as a last resort when UCs rights under a strong patent have been egregiously violated. Under the "third window," a patent infringer could then place UCs patent into post-grant review, not because of any real concern over the validity of the patent, but rather, simply to delay the enforcement of UCs valid patent rights and to buy itself more time to infringe in the marketplace. Given the very high stakes in patent enforcement and litigation, UC fears that the "third window" will simply become another way for parties who do not respect intellectual property rights to abuse the system.

## 2. Any Post-Grant Review Process Must Ensure Validity and Promote Finality

UC is concerned about the addition of language in H.R. 1908 which appears to leave a patent holder open to repeated challenges over the validity of an issued patent over the lifetime of a patent based only on a "preponderance of the evidence" standard presumption that a patent is valid. Such open ended opposition procedures could

discourage companies, especially startups from investing in university technologies because they could not rely on a strong patent to protect their position in the marketplace. By weakening the presumption of validity, fewer university technologies will be licensed and developed into products that can be made available to the general public.

The new Post-Grant Opposition procedure also appears to operate separately from the existing challenges available through the USPTO and through litigation. UC believes that these existing procedures plus a first window of post-grant review would provide sufficient opportunities for opposers to challenge a patent and that allowing opposers to challenge a patent throughout its life undermines the economic usefulness of the patent. In order to give patent holders, such as UC, confidence in the validity of their properlyreviewed patents, there must be some assurance that once the patent has survived a rigorous post-grant review process, it would not be subject to repeated attacks by the same party solely for strategic purposes.

# G. UC Suggests Minor Changes in the Venue and Jurisdiction Proposals (Section 10)

While UC generally supports the proposed amendments to the patent venue and jurisdiction statutes, the Committee may wish to consider adding a separate venue provision for nonprofit educational institutions. A provision allowing nonprofit educational institutions to file suit in patent litigation in any district in which the defendant is subject to the personal jurisdiction of the court would be a helpful addition to H.R. 1908.

In addition, H.R. 1908 permits parties in a patent litigation to file an immediate appeal to the Federal Circuit appellate court of any order from the district court that construes the claims of the patent as a matter of law, known as a *Markman* order," and

requires in such cases that the trial court's proceedings be stayed while the appeal is pending. UC agrees that permitting interlocutory appeals of claim construction rulings to the Federal Circuit could be potentially useful to litigants, and could serve to preserve judicial economy and encourage the strength of issued patents. However, UC is concerned that the interlocutory appeals process could also be used as a delay tactic in the litigation process, and proposes that the stay of the district court's ruling be made discretionary with the trial court judge.

## H. UC Does Not Believe the USPTO Needs Additional Regulatory Authority (Section 11)

H.R. 1908 would provide the USPTO the ability to engage in substantially broader substantive rule making than provided under current law. UC, along with the higher education associations' statement on S. 3818 expressed concern about granting the USPTO expanded rule making authority since this could lead to opportunities for the USPTO to act beyond the scope of what Congress intends through the statutory process. The USPTO already holds fairly broad rule making authority that should be sufficient to engage in the rule making process.

#### I. UC Requests that H.R. 1908 Not Apply Retroactively (Section 13)

UC is concerned that the "effective date" in Section 13 would make H.R. 1908 applicable to any patents issued after the effective date. UC is concerned that the effective date in H.R. 1908 could be made to apply retroactively to patent applications that are still pending at the USPTO at the time the effective date occurs. UC would appreciate it if the drafters would revisit the language of the effective date in H.R. 1908 to specify that it would not to be applied retroactively. The USPTO should also be given adequate time to implement the legislation in an effective and thoughtful manner.

## Conclusion

Chairman Berman, Ranking Member Coble and members of the Subcommittee, thank you again for your leadership, time and attention. We appreciate the opportunity to provide our preliminary comments on H.R. 1908 and look forward to working with the Committee as it considers the legislation. Figures for Testimony by William T. Tucker before the House Committee on the Judiciary, Subcommittee on Courts, the Internet, and Intellectual Property on H.R. 1908, The Patent Reform Act of 2007 April 26, 2007 Page 1 of 1



Figure 1. The distribution of UC start-up companies across industry segments.



Figure 2. Sustainability of UC start-up companies over the last 20 years.