FTC Hearings on the Evolving IP Marketplace
February 12, 2009
Permanent Injunctions and Willful Infringement
Afternoon Industry Roundtable

Introductory Remarks of Donald R. Ware, Partner, Foley Hoag LLP

I would first like to thank the Commission for conducting these hearings and for reaching out to the many constituencies who depend on the patent system to drive innovation and investment. I have been asked today to comment on the recent changes, and proposed changes, in the patent laws from the perspective of two constituencies in particular: universities and small biotech companies. I should make clear that I am not here as counsel for any particular institution or trade association. However, I can speak from considerable experience in representing both universities and biotech companies, and I hope to contribute some helpful insights.

As I will explain, there is a close link between universities and small biotech companies, for together they provide a pathway to take medical innovations from the bench to the bedside. This process depends on the patent system as the engine for technology transfer.

Universities. Let me begin with the universities. Research at American universities is a critical source of both fundamental scientific discoveries and practical applications of technology. This research is a tremendous contributor to economic growth and job creation. In 2007, nearly $49 billion was spent on

research and development at U.S. universities. And that same year, 555 new start-up companies, and thousands of new jobs, were created out of university technology. It is the mission of university tech transfer offices to encourage private sector investment in academic research and then to move that research out into the community where it can benefit the public health and welfare.

The key to commercializing university technology is patent licensing. Before enactment of the Bayh-Dole Act in 1980, industry had very little interest in academic research. But after Bayh-Dole, universities were given statutory authority to patent their inventions and required to diligently commercialize them through for-profit licensees, with a preference for U.S. businesses, and a further preference for small businesses. Since the inception of Bayh-Dole, these licenses have spawned the creation of more than 6,000 new businesses.

Now, where do patent remedies fit into all this? It is very simple. What universities learned before Bayh-Dole, and what Congress recognized in enacting the law, is that without the ability to license out <u>exclusive</u> patent rights, the private sector would not invest. This is especially true with respect to university technology, which typically is early stage and unproven, so that a licensee will need to make substantial and highly risky investment long before it earns a return.

Last year I spent some time on the Hill talking to Congressional staffers about the proposed follow-on biologics legislation, which I know the FTC is also

studying. At first, those on the Hill assumed that universities would not care about whether they could get injunctions to enforce valid patents – after all, aren't they happy just to get a royalty and see their technology used by as many players as possible?. But in fact they do care, and here's why. If the universities cannot offer licensees the certainty of exclusivity over the life of the patent, the licensees' business model collapses, and their willingness to commit substantial resources to developing early stage, high risk inventions of universities into commercial products will vanish.

In a nutshell, based upon decades of experience, universities have found that not just strong patents, but strong patent remedies, are essential to technology transfer and commercialization. Weak patent remedies, by contrast, encourage litigation rather than licensing, and discourage private sector collaboration with universities.

Small biotech companies. In my experience, the same considerations apply to small biotech companies. Small biotech companies (indeed, all but the top ten) account for two-thirds of the industry's pipeline of new biologics. These companies are typically private, rely heavily on venture capital financing, and are years away from FDA approval of a commercial product. The promise of exclusive rights in validly patented subject matter provides the investment

incentive needed to attract the massive amount of capital needed to take a product through clinical trials and regulatory review.

For investors in these companies, the business model assumes enforceable patents for the full term of the patent. Indeed, it is often the last few years of the product's patent exclusivity period when the innovator finally earns a return on its investment. To the extent that changes in the patent system call into question the ability to enforce the right of exclusivity through injunctive relief, venture capitalists will take their funds elsewhere, and small biotech companies will shrink and die rather than grow. This means not only the loss of jobs, but also reduced competition in the marketplace, because it is their ability to enforce valid patents that permits start-ups to compete with mature industry leaders – patents in this context are very much pro-competitive. Finally, and, most tragically, the ultimate result of weakened patent remedies available to small biotech companies is not just less competition and fewer jobs, but also diminished prospects for discovering new biological treatments for our most confounding unmet medical needs. Thank you.

Value of Academic Technology Transfer

FY 2007 AUTM U.S. Licensing Survey:

- $48.8B in R&D expenditures at U.S. academic centers, including $3.4B in industry support
- 5109 licenses/options executed in FY07
- 686 new licensee products introduced in FY07
- 555 new start-up companies based on university technology launched in FY07; 3,388 university start-ups still in business