



**NEW MEXICO BIOTECHNOLOGY  
& BIOMEDICAL ASSOCIATION**

October 8, 2007

The Honorable Pete Domenici  
United States Senate  
328 Hart Senate Office Building  
Washington, DC 20510

Dear Senator Domenici:

I am writing on behalf of the New Mexico Biotechnology & Biomedical Association to express our opposition to S 1145, the Patent Reform Act of 2007, as voted out of the U.S. Senate Committee on the Judiciary on July 18, 2007. Our member biotechnology companies face considerable challenges as they work toward the development of novel biotechnology products and applications in healthcare, alternative energy and agriculture. They do this in the face of a risk-averse investor climate and lengthy and costly research and development timelines. Despite these challenges, our membership still attracts considerable new investment each year based on the promise of their innovative and patented discoveries. S. 1145 could have a far-reaching and negative impact by incentivizing infringement and weakening the enforceability of patent rights. Weakened patent rights drive investment away from risky, capital intensive endeavors such as biotechnology research and development, and the public pays the price. We ask that you oppose S. 1145 in its current form and urge that the concerns with the legislation be addressed prior to any decision to bring the bill to the Senate floor.

The most problematic concerns raised by S. 1145 include:

**Inequitable Conduct Reform**

S. 1145, while attempting to reform the use of the “inequitable conduct” defense, does exactly the opposite. This judicially-created doctrine allows accused infringers to assert that otherwise-valid patents should be declared unenforceable for reason of “inequitable conduct” – an alleged misrepresentation or failure to disclose information to the patent examiner years earlier. This defense is almost routinely raised in patent litigation. While it rarely succeeds, it is a major driver of the cost, length, and acrimony of patent litigation. The fear of being later accused of inequitable conduct also chills patent applicants from communicating openly and efficiently with patent examiners today, leading the U.S. Patent & Trademark Office (PTO) to call for inequitable conduct reform as a foundational element for improving patent examination quality. The National Academy of Sciences has lamented the abuse of this highly subjective doctrine and called for its elimination or reform; while the U.S. Court of Appeals for the Federal Circuit (the Federal court that hears patent appeals) has deemed inequitable conduct claims an “absolute plague.”

Rather than stemming such costly and lengthy litigation abuse, S. 1145 as reported codifies the most criticized aspects of this doctrine. Specifically, the codified materiality standard is so low that virtually any omission or misstatement could be considered material – a standard specifically rejected by the PTO in 1992 when it revised its own internal administrative rules in this area. Moreover, the legislation fails to affect true reform because it still permits unenforceability even

where the misconduct did not impact the granting of the patent. Further, S. 1145 grants a new compulsory licensing remedy that would only incentivize additional attacks on patent owners.

### **Post- Grant Opposition**

S. 1145 creates a new proceeding within the PTO in which third parties are allowed to challenge validly-issued patents administratively instead of having to challenge such patents in court. Under the bill's provisions, patents can be subjected to serial administrative attacks by competitors, under a lower standard of evidence than would be required in court, throughout the entire patent life. Because patents are the linchpin of biotechnology R&D, the increased uncertainty over the patent's reliability created by this process will drive investment away from biotech and to other less risky endeavors, harming our industry's efforts to develop and produce the next generation of products designed to improve global health and the environment.

### **Apportionment of Damages**

The language in S 1145 creates a new regime for awarding damages based upon a "patent's specific contribution over the prior art." This new, untested regime systematically undervalues the bulk of inventive work done in biotechnology because it (i) fixes the marketplace value of an invention at the time the invention was made – not when the patent is infringed, and (ii) attempts to set the commercial value of an invention according to its technological advance over preexisting technology, rather than, as under current law, determining a royalty based on the value obtained by the infringer by utilizing the patented invention. This fundamental shift in valuation will make infringement cheaper, and thus incentivize infringement and discourage good faith licensing of inventions. Additionally, the bill would impose arbitrary limits on when the value of the infringing product may be used as the base for calculation of royalties, which will have great impact in fields such as biotechnology where the infringing product sales is often the most appropriate or only base upon which royalties can be assessed.

We believe that patent reform, if done properly, can truly improve the system for all innovators across the spectrum of American industry. There is broad consensus on many of the reforms contained in S. 1145 that will do just that. Unfortunately, by insisting on the controversial provisions described above, the proponents of this legislation are harming efforts to achieve true patent reform. We urge you to oppose S. 1145, and to also oppose bringing the current legislation to the Senate floor before consensus is reached on these controversial issues.

Sincerely,



Janeen Vilven-Doggett  
President  
New Mexico Biotechnology & Biomedical Association