

## SUMMARY OF U.S. PATENT REFORM LEGISLATION ISSUES

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Outlined below is a list of issues (in approximate order of priority) that were raised in patent reform legislation during the 109<sup>th</sup> Congress. Three main patent reform bills were introduced during this legislative session: H.R. 2795 on June 8, 2005 by Representative Smith (TX), S. 3818 on August 3, 2006 by Senator Hatch (UT) and its subsequent “Substitute” and “Coalition Print”, and H.R.5096 on April 5, 2006 by Representative Berman (CA). None of the bills passed this Congress, but it is anticipated that patent reform legislation will arise again next year. Because the second session of the 109<sup>th</sup> Congress has already ended and the upcoming election next month may have a significant impact on which patent reform issues are raised next year, below is only a brief summary of the issues at this time and more detailed information will be provided later when there is a better sense of what issues will be raised in the near future. The topic in one bill does not necessarily mirror the issues raised on the same topic in another bill, so the topics below should be considered in a general sense. Overall, however, it is important for the university community to be apprised of these issues that either individually or in combination with other issues may significantly alter the basis of the U.S. patent system which is the chosen vehicle in the Bayh-Dole Act to transfer technology from the university laboratory to a commercial partner for development into a product that will benefit the public.

- First inventor to file. Changes the current “first to invent” standard to “first inventor to file,” which means that the patent rights would be issued to the *first* inventor to file for a patent who can provide sufficient evidence for a claimed invention. The current bills maintain a “grace period” for inventions published within a year of filing, but an “absolute novelty” requirement that limits the grace period to publications or disclosures by only the inventor or which are derived from the inventor directly or indirectly has been raised during legislative discussions.
- Injunctive relief. Limits patentees’ ability to get injunctions, directing courts with jurisdiction over patent cases to stay an injunction pending an appeal if it finds that the stay neither will cause irreparable harm to the patent owner nor the balance of hardships from the stay favor the patent owner. Removal of the presumption of irreparable harm would shift the burden of proof to a patent holder to show that money damages alone would not compensate them for harm from infringement. This would harm the exclusive rights of patent holders and make it harder for patent holders to obtain injunctions when infringement occurs. If limited only to a reasonable royalty as monetary damages, one could view this as compulsory licensing. This could significantly hinder a university’s ability to attract a licensee who needs an exclusive position to invest the funds to develop an invention. One of the proposed changes requires the plaintiff to have a product or to be making commercial use of an invention. In the particular case of a university, however, commercialization of an invention must take place through a licensee. Thus the proposed change would deny universities access to injunctions and therefore effective enforcement of university patent rights. This uncertainty would undoubtedly make university inventions less desirable for commercialization.

- Prior user rights. Expands the scope of prior user rights from the current narrow version applying only to business method patents and for an invention that has actually been “commercially used” before the patent filing date to all types of patents and, more subjectively to “substantial preparations for commercial use.” This expansion would weaken patent rights and make it harder for university patent holders to exclude others from utilizing the invention. It would make it more advantageous to practice a given discovery as a trade secret while establishing a defense against infringement.
- Authority of the USPTO. Various provisions in patent reform legislation would expand the authority of the USPTO to make changes to the patenting process. Providing the Director of the USPTO the authority to make changes that are usually subject to patent legislation which provides a thorough airing of the issues by all affected stakeholders. Almost sole authority in the Director could lead to biased or arbitrary changes to the prosecution process, presumptively to reduce the load on the PTO, that may be detrimental to the university community.
- Post-grant review of patent. Establishes a new post-grant opposition system and procedures in the USPTO that would allow a third party to challenge a patent after its issuance. While this would provide a new tool to establish the validity of a patent, the legislative proposals have varying provisions to implement a post-grant review. During the legislative discussions, the university community has not expressed opposition to some form of a post-grant review as long as it is limited in time and the opposer is estopped from raising the same issues in a trial. Some legislative proposals circulating might allow either two windows of opposition (after the patent issues and after a patent infringement lawsuit) or an unlimited window. Another issue raised is whether or not the USPTO has sufficient resources to manage the additional task of processing post-grant proceedings of this nature.
- Infringement by combining components outside the U.S. Repeals § 271(f) of the Patent Act, thereby permitting components manufactured in the U.S. to be combined outside the U.S. for export back into the U.S. irrespective of an infringing component. This removes an important deterrent to overseas infringement activities to the potential detriment of patent holders.
- Apportionment of damages. When an invention is incorporated into a known method or apparatus, provides that damages will be based only on that portion of the total value of the method or apparatus attributable to the invention. While this provision tries to codify case law, judges have sufficient discretion under current law to assess the relative value of a patented technology in determining damages. Legislatively, this does not address the issue of whether a component is the “but for” element which really makes the combination commercially feasible or profitable.
- Continuation applications. Authorizes the Director of the USPTO to regulate the number of continuation applications – subsequent patent applications filed by the same inventor, based on information included in an earlier application, but containing different claims. Filing continuation applications may be necessary to provide additional information that arises

during the course of further research and development or prosecution. Limiting use of continuation applications could have a negative impact on the quality of patents issued and make them more susceptible to attack since information that could be helpful in fully disclosing and claiming a given invention might not be able to be provided to the USPTO. In addition, universities may be advised to delay filing in order to have more complete specifications in the initial application. This, in combination with switching to First Inventor to File, may reduce the university's ability to obtain meaningful and enforceable patents.

- Willful infringement. Reduces the scope of willful infringement by raising the standard of proof required, and limits the amount of damages a patent holder can collect from an infringer. Here again this provision is tantamount to compulsory licensing since it reduces the risk to infringement to a reasonable royalty basis.
- “Best mode.” Eliminates the subjective “best mode” requirement from § 112 of the Patent Act, setting forth objective criteria of the best method of practicing an invention known to the inventor at the time of filing an application. While this change by itself may not be significant, coupled with other changes, such as First Inventor to File and prior user rights, intentional withholding of information may favor the use of trade secret practice. On the other hand, it removes a potential subjective challenge to the validity of a patent.
- Inequitable conduct. This provision would make the USPTO rather than the courts the forum for deciding violations of duty of candor. It would limit the use of inequitable conduct as a defense against patent infringement.
- Venue. Modifies the current patent venue statute to restrict districts in which lawsuits may be brought and in the Senate version of patent reform eliminates a provision that favors universities in choice of venue.
- Prior art. Allows members of the public to introduce new information to the USPTO up to six months after the date of publication of the patent application to challenge the patent and to provide a final quality check. This section also might have inadvertently eliminated the CREATE Act that was passed in the 108<sup>th</sup> Congress as Public Law 108-453 and promotes research collaborations although both the Smith (House) and Hatch (Senate) bills specifically retain the CREATE ACT
- Publication after 18 months. Requires that all patents be published after 18 months. This provision would harmonize with patent laws in other countries. Under current law, one can opt out of the 18 month publication if no foreign patent application counterparts are filed (NAS Report indicates that 10% of U.S. patents fall under this category), but if a foreign application is filed, the application is published in overseas jurisdictions.