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Effect of the Technology Transfer Amendments

1. The amendment repeals subparagraph (a) of the current Section 209. This section requires the license applicant to submit a commercial development plan. It repeals a related provision 209(f)(2) which allows the agency to terminate a license if the licensee fails to execute the commercial development plan. These provisions are important because they give the agency the information it needs to determine the scope of the license and gives the agency a way of making sure that the licensee works towards commercializing the invention. NIH, for instance, uses the commercial development plan to determine the field of use to give the licensee. Often they have inventions which have multiple uses and one company gets a license for a specific use while another gets it for another use or disease. Furthermore, we need to avoid the defensive patent situation where a company with a related invention, gets an exclusive license for a field of use and sits on it to maximize its investment in the related invention. The agency needs the ability to seek other companies as licensees in fields not developed especially if public health and safety is involved.

2. The amendment also repeals the requirement for public notice and for opportunity to file written objections, presumably to allow more expeditious licensing and to allow the licensee to proceed in secret on the exploitation of the license. It also allows pre-existing technologies to be licensed exclusively through CRADAs. This could alter the incentives for companies entering CRADAs in a major way. CRADAs currently do not need to be advertised or competed. This change in law would potentially permit a backdoor way of getting around the notice requirements of Bayh-Dole that allow potential licensees to know that a patent is available for licensing. If this repeal remains in the statute, it would be important to make sure that the agencies would issue their own regulations which gave other potential licensees a chance to make their case for the invention. The flexibility this change would provide is good if it is clear in report language that the agency must come up with its own notice requirement which presumably would be more flexible than the statutory one.

3. The amendment removes the opportunity to file written objections to a licensing. This is viewed as positive by most agencies because current law gives competitors who lost out on the opportunity to license a second chance to object. This is used by some companies to tie up deals by filing spoiler objections. It is better to give all companies a chance up front through a notice of intent to license and after a selection is made, to stick with it.

4. Section (e)(1)(D) of current law, which is repealed by the proposed draft, provides that the proposed terms and scope of an exclusive license are to be no grater than reasonably necessary to provide the licensee with the protection necessary to develop his product. This section is very important to some agencies and less so to others. NIH, for instance, relies on that provision when it licenses only the fields of use that the company needs as shown by its commercial development plan. This provision, when paired with the commercial development plan, permits agencies that have a

variety of companies interested in various aspects of the patent, the opportunity to provide exclusivity in their field of use to a number of companies simultaneously. Therefore, I am sure that NIH will be opposed to this change.

5. The draft language allows for the licensing of inventions; current law allows for the licensing of inventions covered by patent applications. This is a positive move because it broadens the scope of the licensable subject matter. This will be of particular importance in the areas of biological or computer software inventions because there are a fair number of inventions like cell lines or algorithms which have commercial value if licensed but which would not be patented. This also is closer to our jurisdiction. When we rewrote the Bayh Dole Amendments to get them to come to our committee in 1984, we took out the word patents and put in the word inventions to strengthen our jurisdictional case.