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- A. The current law provides that "use[] by others in this country...before the invention [by the applicant of the subject matter claimed in his or her patent application] before the invention thereof by the applicant for patent" is a bar to patentability. [Emphasis supplied.]
- B. The word "use" has been construed as meaning public use-- or –use in public--. Just how public the use has to be is an extremely difficult question and one beyond the scope of this talk.



- C. In addition to the possibility that a prior use of an invention may result in a bar to the patentability of the same subject matter if a different inventive entity subsequently makes the same invention, there is a very complex and very limited personal defense available only to prior users in the United States of "method[s] of doing or conducting business." 35 USC 273.
- D. The current law provides that, if a business method is actually reduced to practice by another inventive entity at least 1 year before the effective filing date of a patent and "used commercially" in the United States before the effective filing date of that patent "whether or not the subject matter at issue is accessible to or otherwise known to the public," that other inventive entity (or, practically speaking, the employer of the other inventive entity) has a personal right to continue using the patented invention commercially.

- E. Note that the prior user right is a personal right. The patent is still valid and enforceable against companies that are not entitled to a prior user right.
- F. There is an exception to the requirement that a prior user right be based on commercial use of the subject matter at issue.
- G. "[A]ctivities performed by a nonprofit research laboratory, or nonprofit entity such as a university, research center, or hospital," if and only if "the public is the intended beneficiary of the use," are statutorily deemed to be commercial uses for the purpose of obtaining the personal right to continue the use.

H. However, the nonprofit research laboratory or other nonprofit entity is only entitled to continue using the subject matter at issue "in the laboratory or nonprofit entity," and the statute specifically provides that the personal defense "may not be asserted as a defense with respect to a subsequent commercialization or use outside such laboratory or nonprofit entity."



II. How Prior Use Will Be Handled Under the AIA

- A. The scope of the personal defense has been broadened. It will be available for "subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process...." The process is not limited to a method of doing or conducting business.
- B. However, the prior user right is still limited to a "commercial process." The defense is limited to a person who, "acting in good faith, commercially used the subject matter in the United States, either in connection with an internal commercial use or an actual arm's length sale or other arm's length of a commercial transfer of a useful end result of such commercial use."

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- C. The other limitations on the prior user right under the AIA are similar to (but not identical to) those under current law.
- D. "[S]uch commercial use [must have] occurred at least 1 year before the earlier of either...the effective filing date of the claimed invention...or...the date on which the claimed invention was disclosed to the public in a manner that qualified for the exception from prior art under section 102(b)."

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- E. The exception for nonprofits has been brought forward in its entirety. However, a limitation on that exception has been added.
- F. The defense is not available to a university or a technology transfer organization whose primary purpose is to facilitate the commercialization of technologies developed by a related university unless "the activities required to reduce to practice the subject matter of the claimed invention could not have been undertaken using funds provided by the Federal Government."

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G. In addition, "Subject matter for which commercial marketing or use is subject to a premarketing regulatory review period during which the safety or efficacy of the subject matter is established...shall be deemed to be commercially used...during such regulatory review period." Note that such regulatory review is normally either completely secret or substantially secret, so this also creates a personal defense based on activities that one's competitors normally know nothing or very little about.

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- H. Although the defense is personal, it can be transferred—but only "as an ancillary and subordinate part of a good-faith assignment or transfer for other reasons of the entire enterprise or line of business to which the defense relates."
- I. Also, such a transfer can only authorize use "at sites where the subject matter that would otherwise infringe a claimed invention is in use before the later of the effective filing date of the claimed invention or the date of the assignment or transfer of such enterprise or line of business."

II. How Prior Use Will Be Handled Under the AIA

- J. The personal defense "extends only to the specific subject matter for which it has been established that a commercial use that qualified under this section occurred, except that the defense shall also extend to variations the quantity or volume of use of the claimed subject matter, and to improvements in the claimed subject matter that do not infringe additional specifically claimed subject matter of the patent."
- K. Also, if the owner of the personal defense abandons commercial use of the subject matter at issue, it cannot later "rely on activities performed before the date of such abandonment in establishing a defense under this section with respect to actions taken on or after the date of such abandonment."

III. Do the Prior User Rights Under the AIA Require the Maintenance of Records Similar to Those Required to Establish Priority in Interferences?

- A. I think that that is a judgment call for each company.
- B. If one needs to establish the date of an actual reduction to practice, one will need the same kind of records. The drafters of the AIA clearly intended the phrase "actual reduction to practice" used in that act to have the same meaning that it has always had in interference practice.
- C. On the other hand, establishing commercial use of the subject matter in question should be easy. Companies cannot do business without records, and the records of commercial use are normally voluminous and easy to access and to prove.