

Notable changes to Section 209 of the Bayh-Dole Act in 2000

KEI Briefing Note
2024:4

Topic	1980, Public Law 96-517 , 96th Congress	2000. Public Law 106-404 , 106th Congress
The word “restrictions” eliminated from the title of the Section	209 Restrictions on licensing of federally owned inventions	209 Licensing federally owned inventions
Confidentiality of development plan “may” changed to “shall” to eliminate agency discretion to treat the plan as privileged and confidential, and not subject to FOIA.	209(a) No Federal agency shall grant any license under a patent or marketing plan. patent application on a federally owned invention unless the person requesting the license has supplied the agency with a plan for development and/or marketing of the invention, except that any such plan may be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code	209 (f) Plan.-- No Federal agency shall grant any license under a patent or patent application on a federally owned invention unless the person requesting the license has supplied the agency with a plan for development or marketing of the invention, except that any such plan shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code.".
Confidentiality of reporting on utilization of the invention “may” is replaced by “shall” to eliminate agency discretion to treat reporting on utilization as privileged and confidential, and not subject to FOIA.on FOIA exemptions, New constraint on reporting: “but only to the extent necessary to enable the Federal agency to determine whether the terms of the license are being complied with”	(f)(1) periodic reporting on the utilization or efforts at obtaining utilization that are being made by the licensee with particular reference to the plan submitted: Provided, That any such information <u>may</u> be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code;	(d)(2) requiring periodic reporting on utilization of the invention, and utilization efforts, by the licensee, <u>but only to the extent necessary to enable the Federal agency to determine whether the terms of the license are being complied with</u> , except that any such report <u>shall</u> be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5 of the United States Code;

Topic	1980, Public Law 96-517 , 96th Congress	2000. Public Law 106-404 , 106th Congress
Interests of the Federal Government	"(A) the interests of the <u>Federal Government and the public</u> will <u>best</u> be served by the proposed license, in view of the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public;	"(2) the Federal agency finds <u>that the public</u> will be served by the granting of the license, as indicated by the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public . . .
Requirement to maintain record of determinations to grant exclusive or partially exclusive licenses eliminated in 2000.	"(e) The Federal agency shall maintain a record of determinations to grant exclusive or partially exclusive licenses.	
<p>In the 2000 Act, minimum public notice requirements were defined as "at least 15 days before the license is granted" and public notices were eliminated entirely for patent licenses made under a CRADA.</p> <p>Prior to the change, NIH public notices on exclusive licenses were typically 60 to 90 days.</p>	<p>in the United States.</p> <p>"(c)(1) Each Federal agency may grant exclusive or partially exclusive licenses in any invention covered by a federally owned domestic patent or patent application only if, after public notice and opportunity for filing written objections,</p>	<p>(e) Public Notice.--No exclusive or partially exclusive license may be granted under section 207(a)(2) unless public notice of the intention to grant an exclusive or partially exclusive license on a federally owned invention has been provided in an appropriate manner at least 15 days before the license is granted, and the Federal agency has considered all comments received before the end of the comment period in response to that public notice. This subsection shall not apply to the licensing of inventions made under a cooperative research and development agreement entered into under section 12 of the Stevenson- Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a).</p>