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# **Cooperative Research and Technology Enhancement**

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This brochure is a guide to the Cooperative Research and Technology Enhancement Act and provides a summary of relevant information about the Act, its implications and its use in academic research programs.

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# THE COOPERATIVE RESEARCH AND TECHNOLOGY ENHANCEMENT (CREATE) ACT

A Guide for Academic Research Institutions

# **Council on Governmental Relations**

The Council on Governmental Relations ("COGR") is an association of leading research universities and affiliated institutions. COGR's primary responsibility is to assist its member institutions in developing policies and practices that fairly reflect the mutual interests and separate obligations of federal agencies and institutions that participate in federally funded research and training programs. It continually reviews the issues for research universities that are inherent in the development and issuance of federal policies, statutes, regulations, and other federal initiatives that impact its members' research programs.

This brochure is a guide to the Cooperative Research and Technology Enhancement Act and provides a summary of relevant information about the Act, its implications and its use in academic research programs. This brochure is not intended to be a comprehensive analysis of the Act and its application in academic research agreements. Rather, it is intended to provide in question and answer format an overview of the Act and its application to research programs with the caveat that due to the passage of time or otherwise, it may not provide a current summary of the Act's interpretation. Accordingly, if legal and/or other professional advice is sought, the advice of a lawyer or other professional should be obtained. This brochure is offered as an aid with the understanding that COGR is not offering legal advice, and COGR cannot and does not warrant the legal sufficiency of the answers to the questions discussed in this brochure.

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# Introduction

The Cooperative Research and Technology Enhancement ("CREATE") Act of 2004 ("the Act") applies to any patent granted on or after December 10, 2004. The Act amends 35 U.S.C. §103(c) of the United States patent law<sup>1</sup> and applies to patents or patent claims developed under joint research agreements ("JRA") as those agreements are broadly defined in the Act. The purpose of the Act is to facilitate the exchange of information pursuant to collaborations by permitting patenting of certain inventions developed as a result of a JRA between two or more separate entities that would not have been patentable prior to December 10, 2004 and would not be patentable without a written JRA. The Act and its implementation can support, if applied correctly, the goals and expectations of joint research relationships between research universities and research institutions with third parties. The unintended results of the Act, however, may restrict or even obstruct the intended goals of a joint research program or the goals of the academic organization or sponsor.

Not too long ago the standard research relationship between academic investigators and their counterparts in industry and elsewhere did not require many communications and exchanges of information in order to undertake a research project, an exchange of materials, or even an exchange of confidential information. In the case of sponsored research, the academic research investigator typically submitted a proposal and the sponsor, institution, and researcher agreed to the final statement of research and research budget. Following the finalization of the research agreement, the research began and it ended when the academic investigator submitted the final research report to the sponsor.

Today, however, research relationships, especially those relationships between academic researchers and industry, are much more collaborative in nature, often requiring meetings, oral and written communications, and interactions between both parties on a frequent basis. Before the Act, the content of the communications between an academic researcher with a third party sponsor or collaborator could be considered "prior art" under the United States patent law.<sup>2</sup> The consequence of finding private communications between two separate parties as prior art is that it may limit the opportunity for either party to obtain a valid patent on technology developed or learned as a result of the communications between the two parties. The Act simply allows patent applicants to exclude certain information from being considered as prior art, expanding the range of patents that might be obtainable. Congress passed the Act to negate and rectify a series of court decisions and certain U.S. Patent and Trademark Office (USPTO) decisions that found that patents or patent claims were unpatentable because they were considered prior art under the U.S. patent law<sup>3</sup> when the prior art was learned or developed between two separate parties working collaboratively in a research program. Congress's intended purpose in passing the CREATE Act

<sup>&</sup>lt;sup>1</sup> As of the date of this brochure proposals were expected to be introduced in the Congress that would amend various aspects of U.S. patent law. If enacted, these proposals could affect the content and placement of the CREATE Act. All statutory references to the CREATE Act herein refer to the status of the law as of March 1, 2007.

<sup>&</sup>lt;sup>2</sup> A patent or a patent claim cannot issue under U.S. patent law if it violates 35 U.S.C. §102 (i.e. if there is "prior art") and specifically 35 U.S.C. §102 (e),(f), and (g) and 35 U.S.C. §103. Both of these sections are discussed in more detail in this Guide. For more information on prior art, see Section I.

<sup>&</sup>lt;sup>3</sup> 35 U.S.C §§102 and 103.

is "to ameliorate the effects of the Oddzon Federal Circuit decision<sup>4</sup> by clarifying Congress's intent to permit the patenting of inventions that result from collaborative or team research"<sup>5</sup> One effect is to level the playing field between research entities and consortia engaged in team research and large corporations with regard to the patentability of inventions resulting from disclosures among the research participants.

There are many strategic considerations in applying the Act to JRAs. Ideally the academic organization's research administrators, legal counsel, and/or university technology licensing officers should carefully consider in advance the goals of a joint research program and the importance of retaining the ability to participate in the patent process on inventions that are developed as a result of the various communications between the university and its research sponsor or collaborator during a JRA program. It also is important that they understand the potential implications of the Act for other types of agreements, and the potential pitfalls that could result from application of the Act in a variety of situations. Due to the complexity of these issues, good communication between sponsored research and technology licensing personnel in research institutions is essential in order to capture the benefits (and avoid the pitfalls) of CREATE. Among the considerations for institutions are whether to approach these issues by developing standard policies vs. handling them case-by-case, the degree and scope of training for personnel in sponsored research and technology transfer offices on CREATE, and development of related management practices.

The following questions and answers relating to the Act are intended as a guide for research universities and research institutions when considering their approach to use of the Act.

<sup>&</sup>lt;sup>4</sup> Oddzon Products Inc. v. Just Toys, Inc. 122 F3d 1396 (Fed. Circ. 1997).

<sup>&</sup>lt;sup>5</sup> House of Representatives Rep. No. 108-425, at 2 (2004).

# I. U.S. Patent Law and the CREATE Act.

# Questions:

### 1. When is an invention patentable under the U.S. patent law?

A patentable invention must meet four requirements. The invention must be: (1) of statutory subject matter; (2) useful; (3) novel; and (4) non-obvious.<sup>6</sup> For the purposes of this Guide and discussion of the Act, the third and fourth required factors "novelty" and "non-obviousness" will be discussed in more detail below.

### 2. How is "novelty" defined under the U.S. patent law?

A patent must disclose *new* subject matter. The subject matter of a patent must be novel and a person shall be entitled to a patent UNLESS:<sup>7</sup>

- (a) the invention was known or used by others in this country; the invention was described in a printed publication anywhere in the world before the invention by the patent applicant;
- (b) the invention was patented or described in a printed publication anywhere in the world or was in public use or on sale in the U.S. more than one year prior to the date of the U.S. patent application;
- (c) the inventor abandoned the invention;
- (d) the invention was first patented or a patent application was first filed on an invention in a foreign country prior to the date of the U.S. patent application;
- (e) The invention was described in a patent application before the applicant made the invention or a patent was issued in the U.S. prior to the invention being made by the applicant;
- (f) the applicant did not invent the subject matter in the patent application;
- (g) during the course of an interference, another inventor involved establishes that he/she is the first inventor and has not abandoned, suppressed or concealed the invention. First to invent can be established through an interference process, which is a proceeding with the U.S. Patent and Trademark Office to determine who was the first inventor between two or more parties claiming patentably indistinct subject matter or as the basis of a patent invalidity finding by a court or administrative body such as the USPTO.<sup>8</sup>

<sup>&</sup>lt;sup>6</sup> 35 U.S.C. §§101, 102, 103.

<sup>&</sup>lt;sup>7</sup> 35 U.S.C. §102.

<sup>&</sup>lt;sup>8</sup> As of the publication date of this brochure legislative proposals were pending in the U .S. Congress that would make significant changes in these provisions.

### 3. What does non-obviousness mean under the U.S. patent law?<sup>9</sup>

The requirement that an invention must be non-obvious "turns on whether a hypothetical person with ordinary skill and knowledge in the art to which the invention pertains with full knowledge of all the pertinent prior art, when faced with the problem to which the claimed invention is addressed, would be led naturally to the solution adopted in the claimed invention or at least would naturally view that as an available alternative."<sup>10</sup>

#### 4. What does "prior art" mean?

For the purposes of this Guide, "prior art" refers to information that is known or becomes known as defined at 35 U.S.C. §102 (novelty) and §103 (obviousness) as summarized above at Section I, Questions 2 and 3, and would prevent an issuance of a patent or a patent claim. When a patent or a patent claim is issued by the U.S. Patent and Trademark Office, the patent holder is granted the right to exclude others from practicing the protected invention. In other words, the patent owner of a U.S. patent has the exclusive rights to prevent others from making, using, and selling the claimed invention during the patent's term in the U.S. The balance between the grant of these broad and exclusive rights to the owner of an issued patent and the right of the public to use the technology is that a patentable invention must be a "*new* and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof...."<sup>11</sup> If a patent application or a claim is determined not to be "new" as required by 35 U.S.C. §102 and §103 and as summarized in this Guide at Questions 1, 2, and 3 above, the technology claimed in the patent and/or in a patent claim is considered to be insufficiently distinct from the prior art and is not patentable because it was anticipated by the prior art.

# 5. What are the recent cases and recent legislative history of prior art that led to the enactment of the Act?

A. The Court of Customs and Patent Appeals (predecessor to the present Board of Patent Appeals) decision <u>In re Bass<sup>12</sup></u> found "that an earlier secret invention by a coemployee constituted prior art with respect to a later invention made by another employee of the same company."<sup>13</sup> This decision led to the amendment of 35 U.S.C. §103 in 1984 to provide that inventions made by employees and consultants with a duty to assign to the same entity would not bar patentability and would not be considered as prior art under Section 102.

B. The Federal Circuit Court held in the <u>Oddzon<sup>14</sup></u> case that confidential disclosures of information by a separate entity or person of any subject matter pertaining to an invention

<sup>&</sup>lt;sup>9</sup> 35 U.S.C. §103

<sup>&</sup>lt;sup>10</sup> Chisum on Patents, Vol. 2, §5.04(1).

<sup>&</sup>lt;sup>11</sup> 35 U.S.C. 101. Note: emphasis is added by author.

<sup>&</sup>lt;sup>12</sup> In re Bass, 474 F2d 1276 (CCPA 1973)

<sup>&</sup>lt;sup>13</sup> White Paper on the Create Act: Utilize and Neutralize, 2006, Wolf, Greenfield and Sacks, P.C. Edward Gates, Esq. and Liza Vertinsky, Esq., pg. 3. For copies, contact Wolf, Greenfield at info@wolfgreenfield.com.

<sup>&</sup>lt;sup>14</sup> Oddzon Products Inc. v. Just Toys, Inc., 122 F3d 1396 (Fed. Cir. 1997).

(See Question 2 above) can be included as prior art when determining whether the invention is obvious under 35 U.S.C. §103 (See Question 3 above).<sup>15</sup>

#### 6. Why did Congress pass the Act in 2004?

Similar to the patent law amendment that followed the <u>In re Bass</u> decision, Congress's intent was to amend the law to protect communications between collaborating research parties from being determined to be prior art, rendering certain inventions resulting from the collaboration unpatentable under the U.S. patent law. The Act excludes from prior art subject matter defined under 35 U.S.C. §102(e), (f), and (g) and §103 (See Questions 2(e), (f), and (g) and 3 respectively above) for determining the non-obviousness of an invention when there is no common ownership of the invention. The Act does not modify the requirements for joint inventorship or joint ownership of a patentable invention.

### 7. Where can the Act be found in the U.S. patent laws?

The Act can be found at 35 U.S.C. \$103 (c) (2) and (3). It appears as a subset to the language that was added in 1984 regarding duty to assign to the same entity (see Question 5 above; also see footnote 1). See Appendix B for the full text of the Act.

<sup>&</sup>lt;sup>15</sup>White Paper on the Create Act: Utilize and Neutralize, 2006, supra pg. 5.

# II. When and what does the CREATE Act apply to?

Questions:

## 8. When did the Act take effect?

The Act applies to patents granted on or after December 10, 2004 that are based on inventions made during the term of a JRA and within the scope of the JRA.

# 9. What does the Act apply to?

When subject matter of an invention is found to have prior art that renders the invention obvious or not novel under 35 U.S.C. §102 (e), (f), and (g) and §103 (See Questions 2(e), (f), and (g) and 3 respectively above), the invention will not be precluded from being patented if the invention was made, owned or subject to an obligation of assignment to the same person (See Question 11 below for a discussion of "to the same person") as the creator of the prior art or if the invention was made during the term and within the scope of a JRA as defined in the statute (see Question 12 below).

## 10. Does a patent application need to state that it is subject to the Act?

The filing party of a patent application may, but is not required to, include the names and the specifics of the JRA in the specifications for the patent application at the time the application is filed. Such JRA information in the patent specification, however, may instead be added at the time the filing party receives notice that the patent application or certain claims within the patent application have been rejected based on 35 U.S.C. §102 and §103. The benefit of the Act is that it saves claims in the patent application that would have otherwise been rejected based on a collaborator's prior art as defined at 35 U.S.C. §102 and §103. When a filing party receives a prior art rejection of a claim, if covered by the Act the filing party can provide a statement to the effect that: (i) the prior art and the claimed invention were made by or on the behalf of parties to a JRA, (ii) the JRA was in effect on or before the date the claimed invention was made, and (iii) the claimed invention was made as a result of the activities undertaken within the scope of the JRA. Under the CREATE Act, the patent application specifications can be amended after payment of a fee that will vary depending on the timing of the revisions to the patent application's specifications.

## 11. What does "owned by the same person" mean under the Act?

For purposes of the CREATE Act, "Owned by the same person" or "subject to an obligation of assignment to the same person" means<sup>16</sup>:

<sup>&</sup>lt;sup>16</sup> 35 U.S.C. §103 (c) (2) and (3) (the Act)

- A. the claimed invention was made by or on behalf of parties to a JRA that was in effect on or before the date the claimed invention was made;
- B. the claimed invention was made as a result of activities undertaken within the scope of the JRA; and
- C. the application for patent for the claimed invention disclosed or is amended to disclose the names of the parties to the JRA.

Communications and inventions that develop under a JRA are considered to be "owned by the same persons" for the purposes of determining what constitutes prior art even though there are two or more distinct parties to the JRA. "Owned by the same persons" for this purpose does not mean that both parties to a JRA jointly own an invention but because the CREATE Act is now part of 103(c), such "joint ownership" for the purposes of the Act is used for the sole purpose of determining whether the invention is novel and not obvious as required by the U.S. patent law for parties not participating in a JRA. For additional information on novelty and non-obviousness under the U.S. patent law see Section 1 of this Guide. The Act does not modify the requirements under U.S. patent law for joint inventorship or joint ownership.

# III. What types of agreements qualify as being a Joint Research Agreement (JRA) under the Act?

# Questions:

### 12. How is a JRA defined under the Act?

The Act defines a "JRA" as "a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention."<sup>17</sup>

# 13. Does the written agreement between the academic institution and a contracting party need to state that the agreement is a JRA under the Act?

No. The written agreement does not need to state that it is a JRA under the Act. However, if the parties agree, the JRA may state that it is the parties' intention that the JRA qualifies as a JRA under the Act. But, regardless of what may be stated in the agreement, if it does not involve any kind of research collaboration at all, it may not be subject to the Act even if the parties state it should be governed by the Act. In order for a research agreement to qualify as a JRA under the Act, the written agreement must be for the performance of experimental, developmental or research work. The benefits of the Act can be utilized unilaterally and without notice by any JRA party to the other party. To benefit from the Act, the claimed invention must fall within the scope of the JRA.

### 14. Can a JRA party prohibit or limit another JRA party's unilateral use of the Act?

Yes. The JRA parties can limit each other's rights under the Act by specifically agreeing in the JRA what the limits will be. For example, the JRA can state that "Neither party may invoke the CREATE Act with respect to any invention that is developed pursuant to this Agreement without the prior written consent of the other party, such consent to include specific reference to the invention for which the benefits of the Act are claimed."<sup>1819</sup>

# 15. What should be done if a JRA party wants to ensure that the Act applies to a specific JRA?

The JRA must: (a) be in writing, (b) for the purpose of research, development or experimental work; (c) the statement of work must be broad enough to cover any anticipated inventions under the JRA; and (d) the JRA can state, but is not required to state, that the Parties intend that the JRA is in compliance with the requirements of the Act.

<sup>&</sup>lt;sup>17</sup> 35 U.S.C. §103(c)(3).

<sup>&</sup>lt;sup>18</sup> Wolf, Greenfield and Sacks, supra, pg 14.

<sup>&</sup>lt;sup>19</sup> See Appendix A for other sample clauses.

# 16. What sections of a written agreement can define that the agreement is for experimental, developmental or research work (and in the same field as an invention)?

There may be many sections in a written agreement that could define whether an agreement is for experimental, developmental or research work. Some examples of appropriate sections in a written agreement are: recitals or whereas clauses, statement of research, publication, and intellectual property and licensing clauses. The invention needs to be in the same field as the work set forth in the JRA.

### 17. What entities can be parties to a JRA?

The Act does not restrict the types of parties subject to the Act. They can both be from the same type of organizations or can be from different types of organizations. For example, some of the different types of organizations can be: academic institutions, nonprofit research organizations, for-profit corporations, government units, foreign entities, or foundations.

#### **18.** Does a "JRA" refer only to a sponsored research agreement?

No. A JRA that supports experimental, developmental or research work may be a sponsored research agreement but it can also be for example: a collaboration agreement with or without funds, license agreement, material transfer agreement, inter-institutional agreement, equipment loan and lease agreement, visitors or visiting faculty agreement, CRADA, non-disclosure agreement or other type of agreement. The Act does not require that all parties actively participate in the research; only that the work be subject to a "written contract, grant or cooperative arrangement...for the performance of experimental, developmental, or research work."

### 19. What agreements might, even inadvertently fall within the scope of the Act?

It depends. For example, in some circumstances license agreements also transfer technical knowledge or "know-how," and also may provide for consulting services by the inventors. Since such agreements might meet the definition of a JRA, the advantages and disadvantages of invoking the CREATE Act should be considered and addressed in the agreement. Material Transfer Agreements and Non-Disclosure Agreements also could meet the JRA criteria.

# 20. Are there ways to ensure that the CREATE Act will not apply to agreements where a party does not intend its application and/or can the effects of the CREATE Act be addressed in such agreements?

Yes. Specific language can be included in agreements to exclude CREATE Act application or address potential issues resulting from the CREATE Act. Appendix A contains sample clauses that may be considered for different types of agreements.

# IV. What are the benefits of the CREATE Act?

# Questions:

# 21. Does the Act allow patents to issue on inventions that would not issue without a JRA?

Yes, this is the essential feature of the Act If one party to the JRA files a patent application (with or without notice to the other JRA parties) on an invention that falls within the scope of the JRA, they may be able to obtain a patent on technology that would have otherwise not been issued because the invention was determined to be obvious or not novel under 35 U.S.C. §102 (e), (f) and (g) and §103 based on subject matter belonging to one of the other parties to the JRA. The filing party "will be able to exclude its pre-existing know how and patents (and the collaborator's pre-existing know how and patents."<sup>20</sup> This applies regardless of whether the prior art is published or unpublished.

### 22. Does the Act encourage the exchange of information between the JRA parties?

Yes. One of the benefits of the Act is that information exchanged between the parties of a JRA will not be considered prior art, which could facilitate the exchange of confidential technical information between the researchers. The exchange of technical information between JRA parties without fear of losing a party's patent position may encourage heightened innovation and the development of new technologies that may benefit the public.

### 23. Can the Act help when negotiating a JRA?

Yes. The Act could provide significant patent benefits to collaborators who value incremental improvements to their existing technologies or to the existing technologies of their joint research partner. The Act allows patent protection for certain incremental improvements made to another party's technology. No approval is needed from the JRA parties, unless the JRA states otherwise, to obtain the benefits of the Act.

#### 24. Does the Act reduce the risk of inequitable conduct during patent prosecution?

Yes. There is already a duty to disclose all information known to be material to the patentability of each claim in a patent application. (37 CFR \$1.56). The Act removes the need to disclose secret information of other collaborators when prosecuting patent applications for inventions arising from a JRA.<sup>21</sup>

<sup>&</sup>lt;sup>20</sup> Wolf, Greenfield and Sacks, supra, pg. 6.

<sup>&</sup>lt;sup>21</sup> Id, pg. 7.

# V. What are they potential hazards of the CREATE Act?

# Questions:

# 25. When will a JRA party know that its JRA is being used as the basis to defend the issuance of a patent claim or patent?

A JRA party may never know that the Act and the agreement are being used as a defense to support the issuance of a patent claim. Unless the JRA requires any party to notify or seek approval from the other(s) before using the Act, requires approval for the use of each party's name, requires permission for the disclosure that a JRA exists or requires permission to disclose the research work, a JRA party may not learn that its JRA is subject to the defense of a patent application. Absent CREATE, such disclosure restrictions typically would not be found in university agreements.

# 26. Could one JRA party effectively be blocked by another JRA party from developing its own patents?

Yes, to the extent that a JRA party obtains a patent covering an improvement over an invention patented by the other party, the effective licensing of the original technology could be blocked. The purpose of the Act is to exclude certain information from being considered as prior art under 35 U.S.C. §§102 (e), (f), and (g). For example, if a university files a patent application for technology not developed under a JRA and a company files a patent application that qualifies as an invention under the Act, the company may be granted a patent for an incremental improvement to the university's original patent. However, the patented incremental improvement may block the university from licensing its own patent if the incremental improvement (which without the Act would not have been patentable) to the university's patent is found to be necessary for most commercial applications. For example, a company files for and obtains with the benefit of the Act a patent that would be considered under the U.S. patent law an obvious incremental improvement to a university's patent. The company's issued patent effectively may block the university from further developing or licensing the university's patents because of the company's blocking patent. See also Question 33 below.

# 27. If a patent is issued based on the Act, does the owning party need to pay royalties or obtain a license from the non-owning JRA party?

Yes and No. The JRA party who is granted a patent based on the fact that its invention was developed under a JRA does not need to pay any royalties to another JRA party for the use of that patent, unless otherwise agreed to in the JRA or separate agreement. If, however, the JRA party who has obtained the "JRA Patent" is also practicing the patents of another party in the JRA, they would need a license to do so and would likely have to pay royalties.

# 28. What if the parties have agreed for a particular research program to place all of the intellectual property developed under the program in the public domain?

If the parties have agreed to place intellectual property created in the performance of a research program in the public domain, the parties may want to consider specifically stating in their research agreement that one party cannot unilaterally invoke the Act without approval of the other party when one party will receive the research results first, prior to the results being placed in the public domain.

# VI. Are there any taxable implications for academic organizations under the CREATE Act?

# Questions:

### 29. Are there any tax implications for academic organizations when using the Act?

Maybe. As of the printing of this Guide there is yet no consensus among tax attorneys or bond counsel as to whether a for-profit JRA party who is able to obtain exclusive ownership of an invention that it develops based on communications and expertise of the non-profit organization within a JRA is obtaining commercial benefits that could be considered a taxable event for non-profit organizations. In order to retain its favorable tax treatment, a university must ensure that it satisfies certain restrictions on the extent and nature of commercial (and off mission) activities that it conducts and income it earns. Research institutions are encouraged to consult with their bond or tax counsel.

#### 30. What are the tax issues that may impact academic organizations under the Act?

One possible tax consequence based on the implementation of the Act under a JRA would be if the research was conducted in a tax-exempt bond financed building and it was determined by an academic organization's tax and/or bond counsel that the commercial party to the JRA was obtaining commercial benefits from the activity in the ownership of intellectual property that a non-JRA member could not obtain. In that case, the research might be considered commercial in nature which might threaten the tax-exempt status of the facility.

# VII. The Act and Double Patenting and Terminal Disclaimers

# Questions:

### 31. What is meant by "double patenting"?

The double patenting doctrine prohibits "one person from obtaining more than one valid patent for the same invention or obvious modifications of the same invention."<sup>22</sup> The purpose of the double patent doctrine is to "prevent an inventor from effectively extending the term of exclusivity by the subsequent patenting of variations that are not patentably distinct from the first patented invention."<sup>23</sup>

### 32. What is a terminal disclaimer?

A patent applicant may, on payment of a fee, file with the U.S. Patent and Trademark Office a disclaimer of any patent claim that it has learned or that the U.S. Patent and Trademark Office has determined is invalid because of the doctrine of double patenting.<sup>24</sup>

### 33. How does the Act impact the filing of terminal disclaimers?

In the event that a claim(s) in a JRA party's patent application is/are obvious in light of claims in another JRA party's issued patent, the second patent applicant must file a terminal disclaimer invoking the Act and requiring the earlier issued patent and the pending patent application to be treated as if they were both commonly owned, thus limiting the term of the second patent such that it expires on the same date as the first one For example, if a company's application is granted before a university application, and claims in the university application are obvious in light of company's application, the university will be required to file a terminal disclaimer in order to obtain the university patent, and the university will need to agree not to enforce the resulting university patent separately from the company patent. Even though the company patent may have been an incremental improvement to the core university application, the university may have given, under these circumstances, effective control to the company over the enforcement of a university patent.<sup>25</sup> The inability to separately enforce would mean that the university (and its licensee) would be unable to enforce the university's patent against a third party if the company were already enforcing its patent against that party.

<sup>&</sup>lt;sup>22</sup> Chisum on Patents, Volume 3A, section 9.01.

<sup>&</sup>lt;sup>23</sup> Applied Materials Inc. v. Advance Semiconductor Materials America, Inc., 98 F3d 1563, 1568, 1577 (Fed. Cir. 1996)

<sup>&</sup>lt;sup>24</sup> 35 U.S.C. §253 and 37 CFR §1.321(c)

<sup>&</sup>lt;sup>25</sup> White Paper on The Create Act: Utilize and Neutralize, supra, pg. 8.

### <u>Appendix A.</u>

### Sample Clauses

Below are some sample clauses for various types of agreements. These clauses are intended to be illustrative only, and COGR cannot and does not warrant their legal sufficiency or suitability for use in any particular agreement. The appropriate contract language will depend on the objects of the parties and the research and expected research results. Institutions may want to consider approaching use of these types of clauses case-by-case or through developing standard policies for various types of agreements.

### 1. Sponsored Research Agreements

"Neither party may invoke the Act with respect to any invention that is developed pursuant to this Agreement without the prior written consent of the other party, such consent to include specific reference to the invention for which the benefits of the Act are claimed."

"No party shall invoke the CREATE ACT without written consent of the other party. In the event that a party invokes the Act without such prior consent, any patent issued arising out of such invocation will be owned by the non-invoking party (or jointly owned by the parties)."

"The parties shall not invoke the CREATE ACT to overcome a rejection of any claimed invention unless that invention is jointly made by the parties."

### 2. <u>License Agreements</u>

"Inventorship of intellectual property generated by access to Licensor's know-how and inventions will be determined according to U.S. patent law. However, in the event that Licensee invokes the CREATE Act to overcome any prior art rejections, all patents obtained by Licensee by asserting that this license is a joint research agreement will be jointly owned [or owned by Licensor] and become part of the Licensed Patent Rights."

### 3. Material Transfer Agreements

"Inventorship of intellectual property generated through the use of this material will be determined according to U.S. Patent Laws. However, in the event that Recipient invokes the CREATE Act to overcome any prior art rejection, all patents obtained by Recipient by asserting that this MTA is a joint research agreement will be jointly owned."

#### 4. Non-Disclosure Agreements

"This agreement is not a joint research agreement under the CREATE Act and the Recipient shall not invoke the CREATE Act during patent examination to overcome prior art rejections."

#### Appendix B.

Text of CREATE Act (35 USC Part II—Patentability of Inventions and Grant of Patents)

Sec.103. Conditions for patentability; non-obvious subject matter

c)(1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

(2) For purposes of this subsection, subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if--

(A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;

(B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

(C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

(3) For purposes of paragraph (2), the term ``joint research agreement'' means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.