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CREATE slide presentation at AUTM conference

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Slide presentation on CREATE Act given at AUTM conference

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The CREATE Act – A Double-Edged Sword?

March 9, 2007

Workshop B3

1:30 – 3 p.m.

Overview

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- **Background Leading to CREATE**
- **What is the CREATE Act?**
- **Benefits & Risks**
- **Why is it a Double Edged Sword?**
- **Challenges for Universities**
- **Managing the Risks**
- **COGR Response**
- **Overview of COGR materials**
- **Q&A**

Background – Leading to CREATE

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Collaborations and impact on available patent protection ...

- **Problem of sharing information between collaborators within single entity: *In re Bass* (1973)**
- **1984 & 1999 Amendments: 102(e)(f)(g)**
- **Problem of prior art when collaborating between two entities: *Oddzon Products v. Just Toys* (1997)**
- **Cooperative Research and Technology Enhancement (“CREATE”) Act of 2004**

In re Bass

In re Bass, 474 F.2d 1276 (CCPA 1973)

Holding: Treated earlier secret invention by co-employee as prior art with respect to later invention made by another employee of company

Implication: Confidential information and inventions shared by employees within same company for purpose of creating inventions for their employer could be used as disqualifying prior art under 102(g)

1984 & 1999 Amendments to Patent Statute

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- **Safe Harbor for incremented improvement:**
Subject matter developed by “another” which qualifies as prior art only under Section 102 (e), (f) or (g) will not preclude patentability under Section 103, provided subject matter and claimed invention are commonly owned at the time invention is made.
 - 102(e) (1999)
 - 102(f) (1984)
 - 102(g) (1984)

Oddzon

Oddzon Products Inc. v. Just Toys, Inc., 122 F.3d 1396 (Fed. Cir. 1997)

Holding: Confidential disclosures of information by separate entity or person to inventor (102 (f) subject matter) can be included as prior art for obviousness determinations under Section 103

CREATE Act

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- **Act builds upon 1984 and 1999 Amendments to Section 103, expanding safe harbor to apply in some circumstances where there is no common ownership**
 - **Solving problem people didn't know they had**
 - **Inequitable conduct risk**

What Act Applies To

- **Inventions occurring as result of activities undertaken within scope of “written joint research agreement”**
 - Entered into between any two or more separate parties
 - Entered into prior to invention
- **Overcome rejection under 35 U.S.C. 103 based upon subject matter which only qualifies as prior art under 35 U.S.C. 102(e), (f) or (g)**

What is “Joint Research Agreement” under CREATE?

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- **Between two or more parties**
- **In writing**
- **For performance of experimental, developmental or research work**
- **In field of invention**

Benefits

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- **Obtain patents otherwise precluded by prior art (building IP)**
- **CREATE helps with inequitable conduct problems arising from failure to disclose secret information shared by parties to JRA**

Risks

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- **Act can be relied upon unilaterally**
 - **Blocking patent owned by incremental innovator**
- **Terminal disclaimer constraint**
- **Tax issues**
- **Adds to confusion about how to manage university collaborations, with potential impact on collaborative activity**

Why a Double Edged Sword?

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- **Provides university with opportunity to benefit, but also presents risks**
- **Advantages of CREATE Act**
 - **Encourages exchange of information that otherwise would have been considered prior art before CREATE Act**
 - Allows patents to issue on inventions that would not otherwise have issued
 - **Promotes collaboration between university and separate party (private, public, and non-profit)**

Challenges for Universities under CREATE

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- Increases challenges facing University Research and Technology Transfer offices
- How to weigh potential advantages provided by CREATE Act against **unintentionally**:
 - Providing another party with additional rights and advantages not intended by license or research project; and/or
 - Presenting risks to university

Challenges for Universities *(cont)*

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- **Adds to complexity of issues being addressed by university research administrators**
 - Un-chartered waters
 - No one-size-fits-all solution
- **Research is increasingly collaborative**
 - Visitors, materials, equipment, facilities
 - Company may require negotiation from its agreement

Challenges for Universities *(cont)*

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- **Potentially high stakes – impact of research administrator’s decisions**
 - **Goals of university's research program**
 - Publication
 - Deposits of data in public domain databases
 - **Future patent filings**
 - **Technology transfer opportunities**
 - **Future research opportunities**
 - **May be required to enter into license for research purposes on patent granted with application of CREATE Act**

Challenges for Universities *(cont)*

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- **May not be obvious**
 - **CREATE Act applies automatically to “JRAs”**
(unless altered by contract)
- **Applies to many types of agreements**
 - **Title of agreement is not determinative**
 - **If not part of sponsored research program, does university have review process?**

Challenges for Universities *(cont)*

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Definition of JRA can apply to qualifying written:

- **Collaboration Agreements**
- **NDAAs**
- **Sponsored Research Agreements**
- **Licenses**
- **Inter-institutional Agreements**
- **Material Transfer Agreements**
- **CRADAs**
- **Equipment Loan & Lease Agreements**
- **Visitors or Visiting Faculty Agreements**
- **And more**

Example

Situation:

University and Company X enter into a Visiting Scientist Agreement for Company's scientist to visit and participate in a University research program in Professor X's laboratory.

Example *(cont)*

Specifics:

- **Agreement is silent on CREATE Act.**
- **Visiting Scientist attends non-public University lab meetings and is given access to pre-publication review of University research results.**
- **University lab is located in tax-exempt, bond financed facility.**
- **Professor X's research program is federally funded.**

Example *(cont)*

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Specifics (cont):

- **Company files patent application on its Visiting Scientist's solely made invention on its improvement of University's patentable technology and invokes CREATE Act to exclude University's prior art**
 - **Communications, pre-publication reviews, non-public scientific exchanges**

Example *(cont)*

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Issues for University:

- **Is Visiting Scientist Agreement a JRA?**
- **Does Agreement comply with University policy requiring visitors to assign University ownership of inventions made using University facilities?**
- **Is Agreement consistent with University's obligation to its research sponsors? including federally funded?**

Example *(cont)*

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Issues for University (cont):

- **Is Agreement consistent with goals of Professor X's research program?**
 - **Encourage Visitor's collaborative contributions?**
 - **Dissemination of research results?**
 - Making its research results freely available to the public?
 - Licensing its patented invention?
- **Does Agreement present University with tax consequences?**

Example *(cont)*

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Issues for University (cont):

- **Is Agreement consistent with University's future research goals?**
 - **Impact on future research**
- **Is Agreement consistent with University Technology Transfer Office's strategy for Professor X's invention disclosure?**

Example *(cont)*

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Issues for University (cont):

- **Will Company patent on its improvement limit or block enforcement of University's patent rights on its subsequently filed application for Professor X's core innovation?**
- **Technology Transfer Office may not know of Company's patent application**
- **May impact executed licenses**

Managing Risks of CREATE

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Some “flags” for University research administrators

- **Research Collaborations between University and another party:**
 - For incremental improvement of University’s pre-existing technology
 - Where University is core innovator and is licensing its technology
 - Involving pre-publication access to University research results
 - Involving visiting company scientist to University

Managing Risks of CREATE *(cont)*

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- **Be fully aware of goals of research program**
 - **Focus on Statement of Work and future research goals**
- **Communication with Principal Investigator**
- **Which party(ies) are providing confidential information or materials?**
- **Will company participate without advantages under CREATE Act?**
- **Communication with TLO**

Managing Risks of CREATE *(cont)*

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- **Can risks of CREATE Act be managed through contract terms?**
- **Many variations**
 - Parties agree this is not JRA
 - Provide for joint ownership of invention made using prior art disclosure
 - If CREATE applies, neither party will invoke without consent of other
 - If one party violates, it will assign to non-invoking party

Managing Risks of CREATE *(cont)*

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- **Can risks of CREATE Act be managed through contract terms?**
- **Challenges**
 - **Need to “guess” field of technology development BEFORE development**
 - **Burden to review scope of research activity and make required updates to agreement**
 - For example, where statement of research is amended (i.e., broadened), new parties are added, etc.

Managing Risks of CREATE *(cont)*

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- **Educational initiatives to inform University research community of CREATE Act**
 - Including implications for “informal” collaborations
 - Should parties be conducting their collaborative research under written JRA?
 - If so, need to put this in place before research begins
 - Importance of SOW (not too broad or too narrow)

COGR Response

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- **Have there been different opinions on how to handle?**
- **Decision to develop guidelines**
- **Developing COGR materials**
 - **Main discussion points during development of guidelines**

COGR Materials

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- **Overview of what COGR materials provide**
 - www.cogr.edu
- **Any next steps?**

Q & A

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- **What have you seen in the field?**
- **What has your university done in response to CREATE?**
- **What resources do you think are needed?**