

# The CREATE Act of 2004: Observations and open issues after 18 years

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MARCH 9, 2022

The Cooperative Research and Technology Enhancement (CREATE) Act of 2004<sup>1</sup> was enacted to remove certain obstacles to patenting inventions arising out of collaborative research by individuals at different institutions.

This article provides an overview of observations concerning the Act taken from 18 years of advising clients on its implementation. We discuss the scant case law to date interpreting the Act and also a few open questions relating to joint research agreements (JRAs), statutory and regulatory interpretation, terminal disclaimers and implications for licensing and enforcement.

## Common ownership under a JRA

The CREATE Act amended the Patent Act about eight years before Congress enacted the America Invents Act (AIA<sup>2</sup>). Specifically, the CREATE Act amended Section 103(c) of the pre-AIA Patent Act, 35 U.S.C.A. § 103(c), to specify conditions under which different parties can be treated as common owners for the purpose of avoiding obviousness rejections.

Under pre-AIA § 103(c)(2), subject matter developed by another person that is only available as prior art under pre-AIA 35 U.S.C.A. § 102(e), (f) or (g) is deemed to be commonly owned with a claimed invention when:

- (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.

The AIA eliminated pre-AIA § 103(c)(2), and the conditions under which different parties are deemed to be common owners under a JRA are now found under AIA 35 U.S.C.A. § 102(c). One effect of the change is that a proper showing under AIA § 102(c) excludes subject matter under AIA § 102(a)(2)<sup>3</sup> as being prior art in both anticipation and obviousness rejections rather than just obviousness rejections.

The conditions for common ownership under AIA § 102(c)(1)-(3) mirror those of pre-AIA § 103(c)(2)(A)-(C) with only AIA § 102(c)(1) differing from its pre-AIA counterpart.

AIA § 102(c)(1) states that “the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention.”

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*The CREATE Act has fostered cooperative research among unrelated entities but many issues remain open for interpretation by the courts.*

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The language “in effect on or before the effective filing date” reflects the AIA focus on the effective filing date versus the pre-AIA focus on when the invention was made.

We are not aware of any discussion in the legislative history regarding the reasons for the change from “the claimed invention was made by or on behalf of *parties* to a [JRA]” in pre-AIA § 103(c)(2) (A) to “the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, *1 or more parties* to a [JRA]” in AIA § 102(c)(1). One possibility is that the change was made to explicitly state what was intended by the pre-AIA language.

## What types of documents qualify as a JRA?

The CREATE Act and the AIA define 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>4</sup>

Although the definition of a JRA requires it to be written, there is no required format for the JRA beyond being a contract, grant, or cooperative agreement. Case law has not addressed the format of JRAs.

The legislative history of the CREATE Act indicates that Congress intended the format of JRAs to be flexible, also including JRAs defined by multiple documents.

See, e.g., H.R. Rep. No. 108-425, at 9 (2004), 2004 WL 349693, stating that:

... Congress does not intend to prescribe the specific form of the agreement parties must use to benefit from this Act nor to require the writing be contained in a single instrument.

See also 150 Cong. Rec. S7520-05, S7521 (2004), WL 1430101, stating that:

... evidence of a joint research agreement may take the form of cooperative research and development agreements, CRADAs, material transfer agreements[,] MTAs, or other written contracts or multiple written documents or contracts covering various parties or aspects of the written agreement.

### What needs to be described in a JRA?

While a JRA's format is flexible, the required showings under pre-AIA § 103(c)(2) and AIA § 102(c) arguably are not. See, e.g., H.R. Rep. No. 108-425, at 9 (2004), 2004 WL 349693, stating that:

Congress does intend the writing to demonstrate that a qualifying collaboration existed prior to the time the claimed invention was made and that the claimed invention was derived from activities performed by or on behalf of parties that acted within the scope of the agreement.

Case law has not addressed what level of detail is sufficient to demonstrate that a claimed invention resulted from activities undertaken within the scope of a JRA. But, some initial case law confirms that more is needed than evidence of collaboration between parties or an exchange of materials from one party to another.

In *Promega Corp. v. Applied Biosystems, LLC*,<sup>5</sup> an earlier application assigned to Caltech was used as prior art against a later application listing five inventors, only four of whom had assigned to Caltech before the filing date of the later application.<sup>6</sup> The remaining inventor was employed by Applied Biosystems, not Caltech.<sup>7</sup>

The court found there was no common ownership under pre-AIA 103(c)(1), because Caltech did not have full ownership rights to both applications when the later invention was made.<sup>8</sup>

The court also stated that there could be no exclusion based on a JRA under pre-AIA 103(c)(2) because “[a]lthough Life Tech has proved that Caltech and Applied Biosystems collaborated during the 1980s ... it has not identified any written joint research agreement covering the invention, or argued that such a written agreement exists or ever existed.”<sup>9</sup>

Another family of cases, *Milwaukee Elec. Tool Corp. v. Snap-On Inc.*, 271 F. Supp. 3d 990 (E.D. Wis. 2017) and *Milwaukee Elec. Tool Corp. v. Snap-On Inc.*, No. 14-cv-1296-JPS, 2017 WL 4570787 (E.D. Wis. October 12, 2017), indicates that evidence of a JRA requires more than showing that one party provided parts of an invention to another party.

Milwaukee's invention was directed to a battery pack for a hand-held power tool comprising, among other limitations, a plurality of battery cells.<sup>10</sup> A sales representative of Moli wrote to Milwaukee describing Moli's battery cells and their potential use in high-power applications.<sup>11</sup> A Milwaukee employee met with a Moli representative, and Milwaukee ultimately obtained various battery cells from Moli.<sup>12</sup>

The court found that Moli's battery cells and related evidence were available as prior art under pre-AIA § 102(f) in an obviousness rejection.<sup>13</sup> Milwaukee did not dispute that the Moli evidence failed to qualify as an exception under pre-AIA § 103(c), because Moli was not Milwaukee's employee, and Milwaukee did not execute a JRA with Moli.<sup>14</sup>

While there was presumably a sale contract between the parties, apparently there was no written agreement that Moli's battery cells would be used for experimental, developmental, or research work associated with the production of Milwaukee's battery pack.

The pre-AIA § 102(f) art associated with Moli's sale of parts to Milwaukee is not at issue under AIA § 102(c) as § 102(f), as well as other subsections of pre-AIA § 102, was stricken from the statute.

But, one analogy under the AIA could be when materials are transferred under an MTA from a first party to a second party. If the MTA qualifies as a JRA, then an earlier-filed application by the first party that discloses the transferred material arguably could be excluded as AIA § 102(a)(2) prior art against a later-filed application by the second party.

Many MTAs include sparse language concerning the scope of activities to be taken under the agreement. Thus, while an MTA can qualify as a JRA, as can any written document between parties in theory, it is unclear whether many existing MTA's provide the requisite description for a JRA.

Depending on the availability of transferred material as potential prior art, it could be advisable to include language in an MTA that summarizes the scope of activities that will be undertaken with the transferred material and include some element of collaboration between the parties.

Regardless of a JRA's format, parties should define JRA activities (i.e., experimental, developmental, or research work) that are likely to encompass any invention resulting from their collaboration. A JRA that narrowly delineates the scope of activities runs the risk of excluding an invention that may ultimately result from the exchange.

For example, the Manual of Patent Examining Procedure (MPEP) provides the following hypothetical:

Company A and University B have a joint research agreement (JRA) in place prior to the date invention X' was made but **the JRA is limited to activities for invention Y, which is distinct from invention X**. Professor BB from University B communicates invention X to Company A.

On November 12, 2004, University B filed a patent application on invention X. On December 13, 2004, Company A filed a

patent application disclosing and claiming invention X', which is an obvious variant of invention X. **University B retains ownership of invention X** and Company A retains ownership of invention X', without any obligation to assign the inventions to a common owner.

**Company A could not invoke the joint research agreement provisions of pre-AIA 35 U.S.C. 103(c) to disqualify University B's application as prior art in a rejection under pre-AIA 35 U.S.C. 103(a) because the claimed invention was not made as a result of the activities undertaken within the scope of the JRA.**<sup>15</sup>

While the above hypothetical is drafted to discuss pre-AIA JRAs, it emphasizes the need for the JRA to properly describe the scope of intended work.

In our view, describing the subject matter of the agreement in general terms and including some element of collaboration better ensures that the statutory requirement — “made as a result of activities undertaken within the scope of the joint research agreement” — is met.

Additionally, agreements intended for use as JRAs could explicitly state so, such as: “This agreement is intended to be a joint research agreement within the meaning of 35 U.S.C.A. § 100(h) and 37 C.F.R. § 1.9(e).”<sup>16</sup>

**What if a JRA for a later application involves overlapping but different parties from an earlier application that is cited as prior art?**

Consider the following hypothetical:

Company A and B file a first patent application. Company B and C have a JRA in place prior to filing a second patent application. There is no JRA in place between A, B, and C prior to the second application's filing date. The first application publishes after the second application's filing date, and subject matter from the first application is cited in an AIA § 102(a)(2) rejection against the second application.

Can B and C rely on their JRA to disqualify A and B's application as prior art?

The case law does not address this issue, but we believe the answer is likely no if the subject matter cited from the first application is co-owned by A and B.

In the *Promega* case discussed above, the district court determined there was no common ownership for purposes of pre-AIA § 103(c)(1) between an earlier application assigned to Caltech and a later application in which only four of the five inventors had assigned to Caltech by the time the later application was filed.<sup>17</sup>

The lack of common ownership for purposes of excluding prior art in *Promega* suggests that a court could similarly find that a JRA between B and C would not be deemed to establish common ownership with subject matter co-owned by A and B.

AIA § 102(c)(1) states that “**the subject matter disclosed was developed and the claimed invention was made** by, or on behalf

of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention.” (Emphasis added.)

If A and B are co-owners of the earlier subject matter, then the “subject matter disclosed” arguably only was made “by or on behalf of” A and B, not by or on behalf of just B.

From this, it follows that A also would have to be a party to B and C's JRA in order to exclude subject matter developed by or on behalf of A and B.

However, as there is no case law on point that we are aware of, it is possible that a court could interpret subject matter jointly made by or on behalf of A and B as being individually made by or on behalf of A and B as well.

To safeguard against the former interpretation, an agreement between A and B could state that each will join the other in any subsequent JRA with another party (*i.e.*, C) that involves related subject matter.

**What are the effects and limitations of terminal disclaimers based on JRAs?**

After a JRA is properly invoked to disqualify an earlier-filed patent or application that is cited as prior art against a later-filed application, an ODP rejection based on the cited patent or application can be raised against the later-filed application. The rationale for ODP rejections in these situations is to prevent “the parties to the [JRA] from obtaining two or more patents with different expiration dates covering nearly identical subject matter.”<sup>18</sup>

The applicant of the later-filed application can attempt to overcome the ODP rejection by argument or can submit a terminal disclaimer to obviate the rejection procedurally. With the latter, the applicant disclaims any term of a patent granted on the later-filed application that is longer than the term of the cited patent or any patent granted on the cited application.<sup>19</sup>

But, parties to JRAs should be aware of several potential complications associated with ODP rejections and terminal disclaimers.

**1. No separate enforcement**

A terminal disclaimer that is filed to obviate an ODP rejection based on a cited patent or application that is deemed to be commonly owned under a JRA must:

Include a provision waiving the right to separately enforce any patent granted on that application or any patent subject to the reexamination proceeding<sup>20</sup> and the patent or any patent granted on the application which formed the basis for the double patenting, and that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent and the patent, or any patent granted on the application, which formed the basis for the double patenting are not separately enforced.<sup>21</sup>

We are not aware of case law construing the “not separately enforced” requirement of § 1.321 (d)(3), but the legislative history states that:

The CREATE Act will not require the owner of a first-issued patent or an indistinct patent to enforce any such patent. Rather, the prohibition against separate enforcement described above is necessary to address the sole policy objective of preventing different patent owners from separately enforcing a first-issued patent and a related indistinct patent.<sup>22</sup>

One interpretation is that § 1.321 (d)(3) does not require the owner of a cited patent or any patent granted on a cited application (*i.e.*, the “first-issued patent”) to enforce their patent when the owner of any patent granted on a later-filed application (*i.e.*, the “indistinct patent”) enforces their patent, or vice versa. In other words, either party can enforce their patent without the other party joining in an action against a potential infringer.

The parties, however, cannot each separately enforce their patents against the same potential infringer. Doing so will result in unenforceability of any patent granted on a later-filed application but, based on the language of the rule, will have no apparent effect on enforcement of a cited patent or any patent granted on a cited application.

For this reason, owners of applications that rely on JRAs to terminally disclaim their collaboration partners’ patents or applications should consider negotiating terms that allow for control over enforcement of all patents associated with the terminal disclaimer. In this way, the likelihood of unenforceability due to separate enforcement is decreased.

## 2. ODP rejections based on patents or applications that are not prior art

In its current form, § 1.321(d) only allows for use of terminal disclaimers where ODP rejections are based on earlier-filed patents or applications that have been excluded as prior art under a JRA. The current rule does not address several situations in which an ODP rejection can be based on a patent or application that is not prior art.

For example, an ODP rejection can be raised against: (1) a subject application listing different owners but the same inventors as a reference patent or application,<sup>23</sup> (2) a subject application that has at least one applicant or inventor in common with a reference patent or application filed on the same date, and (3) a subject application that was filed before a reference patent or application.

At present, the only way to overcome ODP rejections based on a JRA in situations where the reference patent or application is not prior art is to petition the USPTO to waive the prior art requirement of § 1.321(d).

On December 30, 2020, the USPTO issued a notice regarding proposed changes to § 1.321(d) that would address the issue by eliminating the prior art requirement of § 1.321(d).<sup>24</sup>

If the proposed amendment is implemented, it will be possible for parties to a JRA to file terminal disclaimers over one another’s

patents or applications that have not otherwise been excluded as prior art, as long as the patents or applications are subject to a JRA as defined by pre-AIA § 103(c)(2) or AIA § 102(c). The enforcement provisions of § 1.321(d) are not substantively altered by the proposed amendments.

But, there is no clear provision in the current or proposed rules that permits filing a terminal disclaimer in an earlier-filed application over a patentably indistinct later-filed application that has a different owner, when only the later-filed application is subject to a JRA between the owners.

Until courts address whether an ODP rejection is proper in such earlier-filed applications, collaborators should be cautious in permitting patents to issue from the later-filed application before the earlier-filed application.

Alternatively, collaborators could negotiate common ownership of the applications so that terminal disclaimers could be filed as needed in either application.

## Avoiding pitfalls

The CREATE Act has fostered cooperative research among unrelated entities but many issues remain open for interpretation by the courts. Until further judicial guidance is provided, collaborators can minimize their risks through careful filing and prosecution strategies.

In particular, parties to a JRA could:

- (1) draft the JRA to describe the intended experimental, developmental, or research work in general terms to ensure that the statutory requirement — “made as a result of activities undertaken within the scope of the joint research agreement” — is met;
- (2) include terms in agreements requiring that if any collaborator enters into a JRA with another party involving related subject matter, then all collaborators will enter into the JRA;
- (3) negotiate terms that provide control over the enforcement of patents associated with a terminal disclaimer filed under a JRA to the party that files the terminal disclaimer; and
- (4) prosecute an earlier-filed application that was not subject to a JRA before prosecuting a patentably indistinct later-filed application that was subject to the JRA, or negotiate common ownership of the applications.

## Notes

<sup>1</sup> Pub. L. No. 108-453.

<sup>2</sup> Leahy-Smith America Invents Act (AIA, H.R.1249), effective September 16, 2012.

<sup>3</sup> Prior art under AIA § 102(a)(2) includes a patent or published application that names another inventor and was effectively filed before the effective filing date of the claimed invention.

<sup>4</sup> See pre-AIA § 103(c)(3), 35 U.S.C.A. § 100(h), and 37 C.F.R. § 1.9(e).

<sup>5</sup> No. 13-cv-2333, 2013 WL 2898260 (N.D. Ill. June 12, 2013).

<sup>6</sup> *Id.* at \*5.

<sup>7</sup> *Id.* at \*6.

<sup>8</sup> *Id.*

<sup>9</sup> *Id.* at \*6.

<sup>10</sup> *Milwaukee*, 271 F. Supp. 3d at 1000.

<sup>11</sup> *Id.* at 1001.

<sup>12</sup> *Id.* at 1001-1005.

<sup>13</sup> *Milwaukee*, 2017 WL 4570787 at \*3-4.

<sup>14</sup> *Id.* at \*4.

<sup>15</sup> MPEP at § 2146.02(III), Example 3 (9th ed. 2019), *emphasis added*.

<sup>16</sup> See 37 C.F.R. 1.104(c)(4)(ii)(A) and (c)(5)(ii)(A), referencing these definitions of JRAs in the exclusion of AIA and pre-AIA art, respectively.

<sup>17</sup> *Promega Corp. v. Applied Biosystems, LLC*, 2013 WL 2898260 at \*5.

<sup>18</sup> See MPEP at § 804.03(I).

<sup>19</sup> See 37 C.F.R. § 1.321(d).

<sup>20</sup> The language “or any patent subject to the reexamination proceeding” refers to situations where the terminal disclaimer is filed during reexamination of a patent rather than during prosecution of an application.

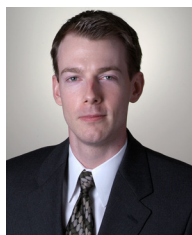
<sup>21</sup> See 37 C.F.R. § 1.321(d)(3).

<sup>22</sup> See 150 Cong. Rec. S7520-05, S7521 (2004), WL 1430101.

<sup>23</sup> Pre-AIA § 102(e) requires a cited patent or application to be “by another,” and AIA § 102(a)(2) requires a cited patent or application to name “another inventor.”

<sup>24</sup> See Disclaimer Practice in Patents and Patent Applications, 85 Fed. Reg. 86518 (proposed Dec. 30, 2020) (to be codified at 37 C.F.R. pt. 1).

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This article was first published on Westlaw Today on March 9, 2022.