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Re: Comments on Interim Rules to Implement the Cooperative Research
and Technology Enhancement Act of 2004 (The CREATE Act)

In response to the Interim Rules for implementation of the CREATE Act, published at 70 Federal Register 1818, the following comments are offered.

As an initial matter, the CREATE Act is clear and the Patent Office does not need to adopt any rules to implement the statute. From the statute, all that is required for an applicant to invoke the safe harbor provisions of 35 U.S.C. §103(c)(2) is (1) amendment of the specification to add the names of the parties to a joint research agreement (JRA) (as permitted by exiting rules) and (2) compliance with 35 U.S.C. §103(c)(2)(A) and (c)(2)(B). As these provisions are clear from the statute, the Interim Rules are thus unnecessary.

As will be detailed below, the Interim Rules also go well beyond the provisions of the statute, thereby not only being improper but also creating unnecessary burdens and restrictions on the intended use of the safe harbor.

Withdrawal or revision of the Interim Rules is thus requested.

1. Interim Rule 1.71(g)(1)(i)

In the commentary, the Patent Office states that applicants will be required to file a statement as evidence of the right to the safe harbor provisions of 35 U.S.C. §103(c)(2). The statement purportedly must aver to the fact that at the time the claimed invention was made, the JRA was in effect. Neither the statute nor the rules, however, require any such statement. If the PTO intends to require such a statement to provide evidence of satisfaction of the requirements of the statute to overcome a rejection, as indicated by the commentary, it should put that requirement in the rules rather than burying it in commentary associated with an interim rulemaking.

Interim Rule 1.71(g)(1)(i) instead requires amendment to the specification that goes far beyond the requirements of the statute (unlike the statement discussed in the commentary addressed above). For example, this interim rule requires amendment of the specification to include the execution date of the joint research agreement (JRA) or to include a reference to where such information can be found in recorded documents. We respectfully submit that this requirement is not required by the statute and is unnecessary.

First, the statute does not require that the specification be amended to include the date of execution of the JRA. The proposed rule thus does not find support in the statutory language.

Second, in the comments, the Patent Office indicates that "The date the joint research agreement was executed must also be provided because this information is necessary to determine whether the 'joint research agreement *** was in effect on or before the date the claimed invention was made' as required by 35 U.S.C. §103(c)(2)(a)." 70 Federal Register 1820. However, the date the claimed invention was made does not correspond to the filing date of the application, and is not discernible from the application file. As a result, requiring disclosure of the JRA execution date does not inform one as to whether or not the JRA was in effect at the time the claimed invention was made. The Patent Office's stated purpose for requiring the specification to be amended to include this information thus is not and cannot be achieved through mere disclosure of the JRA execution date.

As the requirement to include this information in the specification finds no basis in the statutory language itself, and serves no meaningful purpose as discussed above, this requirement should be eliminated from the Rule, and the Rule should instead address a statement that might be necessary to satisfy the statute as outlined in the commentary.

2. Interim Rule 1.71(g)(1)(ii)

Interim Rule 1.71(g)(1)(ii) requires amendment to the specification to include a concise statement of the field of the claimed invention, or to include a reference to where such information can be found in recorded documents. Here again, this requirement finds no basis in the statute and is unnecessary and counterproductive in achieving the goals of the statute.

First, the statute does not require that the specification be amended to include a concise statement of the field of the claimed invention. The proposed rule thus does not find support in the statutory language.

Second, the Patent Office's commentary in support of this rule indicates that it is allegedly necessary in order to determine whether the claimed invention was made as a result of activities undertaken within the scope the JRA as required by 35 U.S.C. §103(c)(2)(B). 70 Federal Register 1820. However, disclosure of this information will not achieve the stated

purpose, as the determination cannot be made from the required information. There is no requirement that the JRA be recorded, and in view of the proprietary information typically included in such agreements, we would anticipate that very few such agreements will be recorded. Accordingly, requiring the specification to include a concise statement of the field of the claimed invention will not inform whether the claimed invention was made within the scope of the JRA.

Third, the claims specify the nature and scope of the invention. Requiring a concise statement on the field of the claimed invention thus could be misleading. This concise statement will thus likely accomplish nothing more than creating unnecessary litigation issues over the potentially limiting effect of the concise statement on the scope of the claims.

Fourth, the field of the invention is often irrelevant to a JRA. A JRA can cover any invention developed as a result of work between the cooperative parties, regardless of the field of the invention. The field of the invention will thus often have nothing to do with the scope of the JRA.

Fifth, here again the commentary requires the applicant to confirm that the claimed invention was made within the scope of the JRA to overcome a rejection on the basis of the JRA. As such a statement will confirm the applicant's compliance with the provisions of 35 U.S.C. §103(c)(2), it is evident that a statement of the field of the invention in the specification is unnecessary.

Thus, as this disclosure is not required by the statute, serves no apparent purpose, and might create unnecessary litigation issues, we submit that this requirement should not be included in the Rule.

3. Interim Rule 3.11(c)

Interim Rule 3.11(c) permits recordation of a JRA or excerpt of a JRA. The Rule requires that for recordation, the submission must include a concise statement of the field of the invention.

For all the reasons discussed in Section 2 above, the requirements for submission of a concise statement of the field of the invention as a prerequisite for recordation of the JRA or excerpt thereof, is unnecessary. Indeed, it makes no sense in the context of recordation of a JRA, where it may be the case that no invention has yet been made, and will often be the case that some inventions to which it will apply have not yet been made. We submit that Rule 3.11(c) should be revised to delete any reference to a statement of the field of the invention.

4. The Statement Required According to the Commentary but Not the Rules

A. Signature of the Statement

As mentioned above, the Patent Office's commentary, without basis in the interim rules, explains a requirement that the applicant "provide a statement to the effect that the prior art and the claimed invention were made by or on behalf of parties to a joint research agreement within the meaning of 35 U.S.C. §103(c)(3), and that the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement." 70 Federal Register 1819.

The commentary continues that "The statement must be signed either by the applicant or by the assignee of the entire interest (as provided for under §3.71(b))." We submit that this language should be revised or clarified to permit the statement to be signed by a duly authorized representative in accordance with the provisions of §1.34.

B. Misuse of the Term "Prior Art" in the Statement

In the statement outlined in the commentary, the applicant will be required to state that the "prior art" was made by or on behalf of parties to a JRA. This use of the term "prior art" is not accurate, and must be revised in implementation of the evidentiary statement in practice. If the safe harbor provisions of 35 U.S.C. §103(c)(2) apply, the subject matter will be disqualified as prior art under 35 U.S.C. §103(a), and thus the characterizing term "prior art" is incorrect.

The term "reference" is instead preferred. This is the term used in the similar evidentiary statement used in association with 35 U.S.C. §103(c)(1). See MPEP 706.02(I)(2)(II).

C. The Commentary Requires a Statement Exceeding the Scope of the Statute

As noted above, the Patent Office's commentary indicates that the statement must be "to the effect that the prior art and the claimed invention were made by or on behalf of parties to a joint research agreement ..." (emphasis added) (70 Federal Register 1819).

There is no requirement in the statutory language requiring the "prior art" (or more accurately the subject matter of the reference) to have been made by or on behalf of parties to a JRA. The statement required by the Patent Office thus goes well beyond the scope of the statute.

The provisions of 35 U.S.C. §103(c)(2) state that "subject matter developed by another person" and a claimed invention will be deemed commonly owned if (A) the claimed invention was made by or on behalf of parties to a JRA 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 a JRA, and (C) the application for the claimed invention discloses the names of the parties to the JRA.

This statute thus references only "subject matter developed by another person." This clearly expressly refers to any subject matter lacking a common inventive entity. The statute is not limited only to subject matter developed by another person and owned by parties to the JRA (as the Patent Office's commentary-required statement limits it in practice), nor is it even limited to subject matter owned by one or more parties to the JRA (which is also clearly within the scope of prior subject matter contemplated by the statute). The above requirements (A), (B) or (C) that must be met to invoke the statute reference only the claimed invention, and require nothing regarding actual ownership of the subject matter that will be treated as commonly owned. This clearly serves the purpose of the statute in promoting JRAs by freeing the parties to JRAs from certain categories of prior art.

Accordingly, the aspect of the statement requiring the applicant to state that the prior art was also made by or on behalf of parties to a JRA is not in accordance with the statute, and in fact goes well beyond the statute, and thus cannot be required by the Patent Office.

Any attempt by the Patent Office to limit the availability of 35 U.S.C. §103(c)(2) to disqualify only that art owned by parties to a JRA would therefore be an improper restriction on applicants beyond the scope of the statute. The restriction attempted by the Patent Office through a practice requiring submission of the aforementioned statement cannot properly be implemented. Any such restriction requires Congressional action to revise 35 U.S.C. §103(c)(2) to limit the statute to subject matter developed by another person and owned by parties to the JRA.

5. Interim Rule 1.71(g)(2)

Interim Rule 1.71(g)(2) requires submission of a processing fee if the amendment of the specification under Rule 1.71(g)(1) is not filed within certain specified periods prior to initial examination of an application or an RCE.

A. No Processing Fee Should be Required

No processing fee should be required, regardless of when the amendment to the specification is filed.

The need for making the specification amendments often will not arise until after substantive examination has begun. There is no statutory purpose in requiring unnecessary disclosure of JRAs to avoid punitive processing fees if the need arises later.

Indeed, the commentary itself recognizes that only "Once an examiner has established a *prima facie* case of obviousness under 35 U.S.C. 103(a), the burden of overcoming the rejection by invoking 35 U.S.C. as amended by the CREATE Act is on the applicant." Because this burden does not arise until after the examiner has established a *prima facie* case, the applicant should not be burdened with requirements to place previously unnecessary statements in the specification under penalty of fees if done later. Indeed, the CREATE Act was not implemented to punish parties to JRAs for not disclosing their otherwise confidential agreements to the public, but to remove unnecessary burdens from them. Thus, imposing a fee for using the benefits of the CREATE Act when the need for such benefits arises unless the parties to the JRA have disclosed to the world their otherwise confidential business agreement is directly contrary to the policy underlying the statute.

In addition, because the Rules apply to all currently pending applications, applicants in many pending applications will have to pay the punitive processing fee in order to take advantage of the newly enacted law. The Rules make no provision for the fact that prosecution has already begun in many pending applications. The implementation of the processing fee without consideration of these many applications is additionally unfair and illogical.

For these reasons, we submit that the processing fee provision of Interim Rule 1.71(g)(2) should be removed.

B. If Required, Additional Time should be Submitted for Filing the Amendment

If a processing fee is retained, the Rule should be revised to permit the amendment to be filed, without a processing fee, if the amendment is filed in a first response to an Office Action that first included a rejection under 35 U.S.C. §103(a) that may be overcome by reliance upon 35 U.S.C. §103(c)(2).

As noted above, the interim rule as written essentially requires the specification amendments to be submitted prior to examination in order to avoid the processing fee or the costs of an RCE.¹ However, as discussed above, it will often not be known whether reliance on 35 U.S.C. §103(c)(2) will be necessary until after substantive examination has begun. Thus, the time frames for amending the specification without a fee appear to be onerous and purely punitive, focusing on requiring disclosure of otherwise confidential JRAs rather than protection

¹ Under 1.71(g)(2)(iv), the processing fee can be avoided after examination has begun if the amendment to the specification is submitted in an RCE prior to a first Office Action in the RCE. While this avoids the processing fee, the RCE fee more than offsets any benefit in filing an RCE in order to avoid the processing fee. Moreover, promoting the prosecution-delaying tactic of filing an RCE over the filing an amendment, as done by the processing fee waiver with the filing of an RCE, is bad policy.

of the parties to JRAs from unpatentability over certain categories of art. Time should be permitted for the required amendment to the specification to be made, free of a processing fee, in response to an Office Action first containing a rejection under 35 U.S.C. §103(a) that can be overcome by reliance upon 35 U.S.C. §103(c)(2).

6. Interim Rule Revising Rule 1.109 Regarding Double Patenting

A. This Interim Rule is Unnecessary and Invalid

The interim rules extensively change Rule 1.109. It is submitted that these revisions to Rule 1.109 are nowhere authorized in the statutory language of the CREATE Act, and constitute an invalid, unnecessary and overly burdensome rule making.

While the legislative history of the CREATE Act may have included references by certain individuals to the need for potentially revising the double patenting provisions (House Report 108-245 (2003) by Congressman Sensenbrenner and Senator Hatch's comments in the Congressional Record (Senate S7520, June 25, 2004)), the language of the statute itself does not address such provisions, and does not authorize the Patent Office to address such provisions.

The legislative history relied upon by the Patent Office in attempting to change Rule 1.109 was merely a statement in the Congressional record of a potential, as yet unrealized, problem.² The fact that Congress took no action in the language of the statute itself to address this allegedly potential problem, and instead merely directed the Patent Office to determine if a need exists to address the potential problem, indicates that Congress ultimately decided that the problem did not in fact need to be addressed at this time.

In fact, the CREATE amendment to §103(c) does not create any double patenting issues. That amendment merely eliminates certain categories of §103 prior art under certain circumstances. It does not authorize, prohibit, or in any way address two parties claiming the same invention or obvious variants thereof. Other statutory sections, notably 35 U.S.C. §135 and §291 address this issue, and provide ways to deal with it. The interim rules conflict with these

² In fact, Senator Hatch's comments state that "the Patent and Trademark Office should exercise its responsibility for determining the necessity for... disclaimers in patent applications..." (S7521). The Patent Office has not undertaken the determination expressed in the Congressional record, and has instead implemented interim rules without any understanding as to whether such rules will actually be required in practice or of the real-world effects of the rules as proposed in areas of contract and conflicts law that are far beyond the expertise of the Patent Office.

statutory systems and in effect overrule them in certain instances. This is obviously not proper, and is neither legal nor necessary.

B. The Terminal Disclaimer Provisions are Excessive and Problematic

Under Interim Rule 1.321(d), both the owner of the rejected application or patent and the owner of the disqualified patent or application must waive the right to separately enforce or license the affected patent properties. This is clearly excessive and unnecessary, particularly in view of current practice under actual common ownership double patenting/terminal disclaimer provisions.

Current provisions in Rule 1.321(c)(3) (addressing terminal disclaimers filed to overcome obviousness-type double patenting rejections under actual common ownership situations) require only that the owner agree that the later issuing patent shall be enforceable only for and during such period that the patent is commonly owned with the application or patent which formed the basis for the double patenting rejection. The owner is not prevented from exclusively licensing any or all of the involved patent(s). As an exclusive licensee of one or more of the involved patents has standing to sue for infringement independently of the patent owner, the current provisions do nothing to prevent multiple litigations for infringement against a single party.

However, the Interim Rule 1.321(d) goes well beyond current practice to bar even this owner/exclusive licensee scenario. There appears to be no legitimate reason for such a far reaching restriction.

The Interim Rule also has the potentially oppressive effect of forcing the owner of a later filed application to obtain signatures from other parties to the JRA (or other unrelated third parties) in order to obtain a patent. If the owner of the prior reference is not cooperative for business or other reasons, the second filing applicant is unfairly prejudiced. This applicant could not resort to an interference to settle first to invent issues because the claims would not be allowable until the double patenting rejection is overcome, and the double patenting rejection could not be overcome because the other party(ies) to the JRA would be unwilling to sign the terminal disclaimer. This could result in the undesirable outcome in which a first to invent party is barred from a patent in favor of a first to file party because of the procedural roadblock posed by the Interim Rule.

The Interim Rule is thus excessive and problematic. We recommend that the Interim Rule be withdrawn and the issues study more extensively by the Patent Office and Patent bar so that an appropriate set of rules, if any, can be crafted. Meanwhile, the present statutory and regulatory scheme appears to provide adequate protection to the public through 35 USC 135(b) and interference practice.

7. Clarification on Retroactivity of the Law Required

The Patent Office stated that the provisions of prior 35 U.S.C. §103(c), now 35 U.S.C. §103(c)(1), previously applicable only to applications filed on or after November 29, 1999, are now applicable to all pending applications regardless of when filed. 70 Federal Register 1819. Thus, if it is desired to overcome a rejection under 35 U.S.C. §103(a) that relies upon commonly owned art available as prior art only under one or more of 35 U.S.C. §102(e), (f) and (g) in an application filed prior to November 29, 1999, it is now only necessary to file a statement that at the time the claimed invention was made, the art and the claimed invention were commonly owned or subject to an obligation of assignment to the same owner. A continuation application to gain the benefits of §103(c)(1) is no longer required, according to the Patent Office's interpretation of the new law. Similarly, according to the Patent Office's interpretation, a reissue application for those patents filed prior to November 29, 1999 and issued after December 10, 2004 to gain the benefits of §103(c)(1) is no longer required.

The CREATE Act states "Section 103(c) of title 35, United States Code, is amended to read as follows..." (emphasis added), then recites the language for both §103(c)(1) and §103(c)(2). The Act continues that "The amendments made by this Act shall apply to any patent granted on or after the date of enactment of this Act" (emphasis added).

The Patent Office appears to be interpreting the Act to mean that deletion of prior §103(c) and addition of similar §103(c)(1) is an amendment made by the Act that applies to all applications pending as of December 10, 2004.

However, it is not clear in the Act that "the amendments" refers to all of §103(c) as opposed to just the language that differs from that of prior §103(c) (i.e., the addition of §103(c)(2)). Thus it is not entirely clear that the Act eliminated the requirement for a filing date on or after November 29, 1999 in order to gain the benefit of prior 103(c). Reliance upon the Patent Office's interpretation of the legislation appears risky. For example, if one were to rely on the Patent Office's interpretation and rely upon 35 U.S.C. §103(c)(1) in an application filed prior to November 29, 1999 without filing a continuation application, there is a possibility that the patent could be found invalid where a court finds the Patent Office's interpretation improper (and thus that the patent did not qualify for the provisions of 35 U.S.C. §103(c), now §103(c)(1), so that the prior art was not in fact disqualified from consideration under 35 U.S.C. §103(a)).

We respectfully request the Patent Office to fully explain its position on why it believes the CREATE Act eliminated the November 29, 1999 filing date requirement for availability of the provisions of 35 U.S.C. §103(c), now §103(c)(1).

8. Rule Making Considerations

The interim rules are premature and violate the Administrative Procedures Act. They should not have been promulgated without prior public notice and comment (5 U.S.C. §553), and should not be enforced.

The commentary with the interim rules justifies the failure to comply with the Administrative Procedures Act by arguing:

The rules of practice, however, do not currently provide for the amendment of an application or the recording of joint research agreements (or excerpts of joint research agreements) to invoke the "safe harbor" provision of 35 U.S.C. §103(c) as amended by the CREATE Act, and do not permit the filing of the type of terminal disclaimer necessary to overcome the double patenting rejection that may arise as a result of the CREATE Act. ...

First, the present rules do permit amendment of the specification, and do not prohibit amendment of the specification to comply with §103(c).

Second, the statute creates neither a requirement nor a need for recording JRAs. In addition, nothing in the present rules prohibits their recordation as "documents affecting title to applications, patents, or registrations" under 37 CFR §3.11.

Third, nothing in the statute requires a terminal disclaimer of any type, or even addresses double patenting issues (as opposed to §103 obviousness issues) at all. Nothing in the statute creates any reason to believe that any "double patenting rejection ... may arise as a result of the CREATE Act.

Section 103 itself clearly establishes what is necessary to invoke its safe harbor provisions, and those provisions can be invoked under the rules existing before the interim rules were published by the PTO. Thus there would be no harm to anyone from the delay inherent in a public notice and comment time period to permit full consideration of the need for, scope of, and effect of rules relating to the CREATE Act.

Furthermore, as detailed above, the interim rules do not merely interpret the statute, but create new substantive obligations over and above any requirements of the statute and in conflict with various other provisions of the patent statutes. Thus the interim rules are not exempt from the Administrative Procedures Act notice and comment requirements, and should not be enforced.

Very truly yours,

/s/
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