

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Docket No. 2004-P-034
RIN 0651-AB76

For: **Changes To Implement the
Cooperative Research and
Technology Enhancement Act of
2004**

70 Fed. Reg. 1818 (Jan. 11, 2005)

***Comments In Reply to the Interim Rule entitled
"Changes To Implement the Cooperative
Research and Technology Enhancement Act of 2004"***

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Sir:

In reply to the interim rule entitled: "Changes To Implement the Cooperative Research and Technology Enhancement Act of 2004," published at 70 Fed. Reg. 1818 (Jan. 11, 2005), the undersigned attorneys and agent at STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. submit the following comments.

Introduction

The Cooperative Research and Technology Enhancement Act of 2004 ("CREATE Act") was enacted into law on December 10, 2005. The U.S. Patent and Trademark Office ("the Office") has issued Interim Rules ("Changes To Implement the Cooperative Research and Technology Enhancement Act of 2004," 70 Fed. Reg. 1818 (Jan. 11, 2005)) to

implement the CREATE Act. The Office has requested that comments regarding the Interim Rules be submitted on or before February 10, 2005.

The undersigned attorneys at STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. respectfully submit that 37 C.F.R. §§ 1.71(g)(1)(i), 1.109(b), and 1.321(d)(4) are not authorized by the CREATE Act, do not reflect Congress' intent in passing the CREATE Act, extend beyond the well-developed case law of double patenting, and/or contravene the purpose of the CREATE Act. Furthermore, these sections will create practical problems for the very applicants whom the CREATE Act is supposed to benefit.

Interim Rules

A. 37 C.F.R. § 1.321(d)(4)

The newly promulgated terminal disclaimer requirement of 37 C.F.R. § 1.321(d)(4) requires both the disqualified patent or application, and the patent that ultimately issues from the rejected application or patent under the joint research agreement (JRA) exemption of 35 U.S.C. §103(c) to be commonly licensed and enforced. Further, the parties must agree that the rejected patent or application and the disqualified patent or application shall be enforceable only for and during such period that they are not separately enforced and are not separately licensed.

1) Forcing the parties to agree that "the rejected patent or application and the disqualified patent or application shall be enforceable only for and during such period that they are not separately enforced and are not separately licensed" improperly prevents the owner of a patent, that later becomes a disqualified patent, from enforcing that patent for acts of infringement that occur after issuance of that patent and before the issuance of the patent that arises from the rejected application.

Enforcement of the disqualified patent for the period from its date of issue until the date of issue of a patent that arises from the rejected application should not be affected by these rules. This was not the intent of the CREATE Act and goes beyond the scope of the

CREATE Act. At a minimum, any rule that ties together the enforcement of the disqualified patent to the patent that arises from the rejected application (*i.e.*, the second patent) must be prospective only from the date of issuance of the second patent, or from the date of the issuance of a Certificate of Correction that corrects the patent to include the names of the parties to the JRA under 37 C.F.R. § 1.71(g)(3).

2) The tying together of the enforcement of the disqualified patent and the patent that issues from the rejected application is beyond the scope of the CREATE Act. Statutory interpretation requires one to "presume that [the] legislature says in a statute what it means and means in a statute what it says there." *Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992). In short, there is nothing in 35 U.S.C. § 103(c) as amended by the CREATE Act that requires or authorizes the common licensing and enforcement provision of § 1.321(d)(4).

3) Furthermore, the common licensing and enforcement provision is not consistent with the case law of obviousness-type double patenting. Prevention of "harassment by multiple assignees" has been recognized as one reason for requiring common ownership for terminally disclaimed patents. *See In re Van Ornum*, 686 F.2d 937, 944 (C.C.P.A. 1982). However, attempting to address this concern by requiring common enforcement and licensing in the unique situation of JRA exemption practice is not practical for the following reasons.

First, the common licensing requirement will often be unworkable. Consider a University that has non-exclusively licensed its patent or published application claiming Invention X to multiple companies for different fields of use. That is, Company 1 has obtained a license from the University for commercializing Invention X for Use 1, Company 2 has obtained a license from the University for commercializing Invention X for Use 2, and so on. After invention X has been licensed to multiple parties, Company 1 develops Invention Y, working with the University within the scope of a JRA. If Company 1's patent application for Invention Y is rejected under 35 U.S.C. § 102(e)/103 over the University's patent or published application, the "safe harbor" of the CREATE Act is unavailable to Company 1 because the University has already separately licensed

the application to Invention X. It would be unrealistic to expect the University to renegotiate existing licenses with multiple parties so that Company 1 could invoke the "safe harbor" of the CREATE Act. In sum, the types of collaborations that Congress intended to promote when enacting the CREATE Act may receive little benefit from this legislation due to the common licensing requirement of §1.321(d)(4).

Second, in light of regulations and/or policies of other Federal agencies, meeting the common licensing requirement of §1.321(d)(4) may prove to be nearly impossible. There are strict requirements for exclusively licensing inventions owned by the Federal government. *See* 37 C.F.R. § 404.7. These requirements include, but are not limited to, publishing a notice of a prospective exclusive license in the Federal Register, determining that an exclusive license is reasonable and necessary for investment in the invention, and giving preference to any small business firms that are interested and capable of bringing the invention to practical application. *Id.* Thus, it will be very difficult, if not impossible, for a company that is collaborating with a Federal agency to benefit from the CREATE Act when trying to patent an improvement that arose out of the collaboration.¹

In addition, current terminal disclaimer practice does not prevent a patent owner from licensing two terminally disclaimed patents to separate parties. For example, an individual may own two patents that claim non-overlapping subject matter, wherein one patent was terminally disclaimed over the other for obviousness-type double patenting reasons. In this example, the non-overlapping subject matter is not patentably distinct. However, the two patents could be separately licensed and would not be asserted against the same infringing activity because the claims are non-overlapping. There is no reason to change this under the CREATE Act and thus it is error to require that two such patents be commonly licensed and enforced.

¹ Consider also that National Institutes of Health licensing guidelines require, with only certain exceptions, the non-exclusive licensing of research tool inventions. *See* Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72090 (Dec. 23, 1999).

4) Finally, the common enforcement provision of §1.321(d)(4) also creates uncertainty. For example, a disqualified patent or published application may broadly claim a first invention, and a patent application that has been allowed by invoking § 103(c)(2) may narrowly claim an improvement. Under §1.321(d)(4), these two patents must not be separately enforced. However, a potential infringer could infringe the patent claiming the broader invention but not the later patent claiming the narrow improvement. Must the patent owners assert both patents even though the owners believe that a third party infringes only one of the patents? Or must the patent owner of the broader patent forgo his right to exclude others from using his patented invention?

Summary: We recommend that the Office delete the common licensing and enforcement requirement of § 1.321(d)(4).

B. 37 C.F.R. § 1.109(b)

Section 1.109(b) requires an examiner to issue a double patent rejection over "a non-commonly owned patent by or on behalf of parties to a joint research agreement in which the inventions claimed in the application or patent under reexamination and in the other patent were made as a result of activities undertaken within the scope of the joint research agreement."

We respectfully submit that Section 1.109(b), as currently written, is overly inclusive. While arguably implicit in the language of the Rule, it is unclear whether an applicant must first invoke the benefit of § 103(c)(2) before an examiner may issue a double patenting rejection. The literal wording of § 1.109(b) would seem to permit an examiner to issue a double patenting rejection over a non-commonly owned patent which the patent applicant did not exclude under § 103(c)(2).

We suggest that the Office amend 37 C.F.R. § 1.109(b) to restrict the applicability of such double patenting rejections. The rule should explicitly state that an examiner may only issue an obviousness-type double patenting rejection if a patent applicant invokes the

benefit of 35 U.S.C. § 103(c)(2). Furthermore, it should be clarified that, once the applicant invokes the benefit of § 103(c)(2) for a particular prior art patent or published application, the examiner is not free to issue additional double patenting rejections based on other patents or published applications owned by a party to the JRA.

We propose that § 1.109(b) be amended to read as provided in Attachment A. Our proposed § 1.109(b) is similar to the interim rule, but with two important differences. First, a double patenting rejection based on a non-commonly owned patent can be made only after the applicant invokes the benefit of the JRA exclusion. Second, the double patenting rejection is limited to the patent disqualified by the applicant.

C. 37 C.F.R. § 1.71(g)(1)(i)

Section § 1.71(g)(1)(i) states that, if an applicant invokes the benefit of 35 U.S.C. § 103(c)(2), "[t]he date the joint research agreement was executed" must be disclosed in the specification of the patent. Alternatively, the patent specification can include "the location where (*i.e.*, by reel and frame number) such is recorded in the assignment records of the Office."

Either available option extends beyond the statutory requirement of the CREATE Act. To claim the benefit of § 103(c)(2), the CREATE Act requires in part that "[t]he 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" 35 U.S.C. § 103(c)(2)(A) (emphasis added). There is no requirement that the applicant disclose the date the JRA was executed. Such information may be confidential, and the disclosure of that information is not required to comply with the statutory requirements of the CREATE Act.

The implementation of § 103(c)(2) should be analogous to what an applicant must do to evidence common ownership under § 103(c)(1) (formerly § 103(c)). For § 103(c)(1), "a statement [by the applicant or an attorney or agent of record] to the effect that the application and the reference were, at the time the invention was made, owned by, or subject to an obligation of assign to, the same person" is sufficient. *See* The Manual of

Examining Procedure ("MPEP"), § 706.02(l)(2).II. An applicant may optionally "submit further evidence, such as assignment records, affidavits or declarations by the common owner, or court decisions, in addition to the above-mentioned statement concerning common ownership." *Id.* An applicant is not required to provide the date an assignment was executed in order to comply with § 103(c)(1). *Id.*

If the Office insists on requiring the submission of the execution date of the JRA, we believe that such disclosure is more appropriately handled under a confidential procedure such as that currently used for the disclosure of trade secret, proprietary, and/or protective order materials. *See* MPEP § 724.02. Disclosure of the execution date of the JRA under the confidential procedures might permit an examiner to confirm that the JRA was executed prior to the date the claimed invention was made, yet not infringe on the confidentiality rights of the patent applicant. Accordingly, Section 724 of the MPEP should be amended to provide guidance in handling submissions of JRAs for purposes of invoking the benefit of § 103(c).

D. 37 C.F.R. § 1.71(g)(3)

37 C.F.R. § 1.71(g)(3) allows for amendment of the specification after payment of the issue fee. However, the comments at Federal Register page 1820, middle column, second paragraph state that the submission of amendments remains subject to the rules of practice, including § 1.312.

The Office has previously noted that § 1.312 does not permit acceptance of an amendment filed after payment of the issue fee, except as waived for documents required by the Office of Patent Publications (Official Gazette notice: 23 March 2004). Rule 71(g)(3) should note that, notwithstanding § 1.312, an amendment after payment of the issue fee may be made.

Conclusion

We respectfully submit that 37 C.F.R. §§ 1.71(g)(1)(i), 1.109(b), 1.321(d)(4) are not authorized by the CREATE Act, do not reflect Congress' intent, extend beyond the well-developed case law of double patenting, and/or contravene the purpose of the CREATE Act. Furthermore, these sections will create practical problems for the very applicants whom the CREATE Act is supposed to benefit.

We request that 37 C.F.R. §§ 1.71(g)(1)(i), 1.71(g)(3), 1.109(b), and 1.321(d)(4) be revisited and amended or deleted as described herein.

Respectfully submitted,
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Attachment A

Proposed 37 C.F.R. 1.109(b)

(b) A double patenting rejection will be made in an application or patent under reexamination if —

(i) an applicant disqualifies as prior art a non-commonly owned patent by or on behalf of parties to a joint research agreement in which the inventions claimed in the application or patent under reexamination and in the other patent were made as a result of activities undertaken within the scope of the joint research agreement; and

(ii) the application or patent under reexamination claims an invention that is not patentably distinct from an invention claimed in the non-commonly owned patent.

This double patenting rejection will be made regardless of whether the application or patent under reexamination and the non-commonly owned patent have the same or a different inventive entity. This double patenting rejection may be obviated by filing a terminal disclaimer in accordance with § 1.321(d).