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VIA EMAIL
VIA FACSIMILE

Mail Stop Comments-Patents
Commissioner for Patents
United States Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Re: Comments Regarding RIN 0651-AB76, "Changes to Implement the Cooperative Research and Technology Enhancement Act of 2004"

Dear Commissioner,

This letter provides comments regarding the Interim Rule referenced above, as published in the 11 January 2005 Federal Register (Fed. Reg. 7:7:1818-1824) for implementation of the CREATE Act of 2004 ("the Act"). Please consider the following comments submitted by Gary D. Colby, a registered patent attorney having the USPTO registration number 40,961.

These comments reflect solely the views and opinions of Mr. Colby, and do not necessarily reflect the views and opinions of Duane Morris, LLP (the firm which employs Mr. Colby) nor of any client, partner, or employee of Duane Morris, LLP.

Regulation of Licensing Rights

Section 1.321(d) of the Interim Rule requires that a terminal disclaimer filed to overcome an obviousness-type double-patenting rejection obligate the owners of the corresponding patents or applications not to "separately license" the properties. The Interim Rule thereby preserves the right of a common owner to separately license patents related by a terminal disclaimer, yet fails to provide this right to the owners of patents related by a terminal disclaimer that refers to a joint research agreement. This dichotomy seems to me to be contrary to the expressed Congressional intent that, *"the requirements under current law for parties to terminally disclaim interests in patents that would otherwise be invalid on "obviousness-type" double patenting grounds are to*

apply, mutatis mutandis, to the patents that may be issued in circumstances made possible by this Act". H.R. Rep. No. 108-425, p. 6.

Insofar as it purports to restrict patentees' ability to license their patents, the Interim Rule exceeds the authority granted to the Office by Congress. The Office has the authority to grant and issue patents. 35 U.S.C. § 2(a)(1). The Office also has the authority to establish regulations to govern proceedings in the Office. 35 U.S.C. § 2(b)(2). The Office lacks authority, however, to regulate the contractual affairs of the owners of issued patents.

The judicially-created doctrine of obviousness-type double-patenting relates to a condition for patentability and must be enforced by the Office. 35 U.S.C. §103(c)(1) was created by Congress for the purpose of encouraging research by permitting a single patent owner to employ collaborative researchers without the danger that the Office will consider the work of the collaborating researchers to be work "by another" for patenting purposes. Common ownership being a condition for invoking § 103(c)(1), it follows logically that the regulation (37 C.F.R. § 1.321(c)) established by the Office to give effect to enactment of § 103(c)(1) includes a requirement that a terminal disclaimer made to avoid an obviousness-type double patenting rejection must include a provision linking enforceability of the resulting patent and common ownership of both the resulting patent and the patent on which the rejection was based.

In the Interim Rule, however, the Office's restriction on future licensing does not follow from 35 U.S.C. § 103(c)(2) as enacted by the Act. Section 103(c)(2) makes no restriction regarding licensing, but instead specifies conditions under which "*subject matter developed by another person*" and a "*claimed invention*" must be considered to be subject to the common ownership provision of § 103(c)(1). The Act does not impose any restriction on licensing activity, nor does it authorize the Office to do so.

Admittedly, it is not immediately apparent how to match the current requirement that a terminal disclaimer under 37 C.F.R. §1.321(c) provide that enforceability of the patent for which the disclaimer is filed depends on co-ownership with the other patent named in the disclaimer with Congress' intention that "*the requirements under current law for parties to terminally disclaim interests in patents that would otherwise be invalid on "obviousness-type" double patenting grounds are to apply, mutatis mutandis, to the patents that may be issued in circumstances made possible by this Act"* (H.R. Rep. No. 108-425, p. 6). There is no indication in the Act or its legislative history that Congress intended that patents related by a terminal disclaimer that refers to a joint research agreement should be separately transferable to different third parties. In the absence of such an indication and in conformity with the expressed legislative intent to conform with current requirements, the prudent course appears to be that regulations enacted to implement newly enacted § 103(c)(2) should alter current regulations to the least extent necessary.

The courts have previously indicated that an important consideration in permitting a terminal disclaimer to overcome an obviousness-type double-patenting rejection is that the resulting patents should remain commonly owned, thereby to prevent a party from being subject to licensing demands from multiple owners of insignificantly distinct patents. The validity of that consideration is not diminished by the Act, except to the extent the Act envisions separate ownership, at least initially, of patents to insignificantly distinct subject matter. A conservative implementation of the Act's requirements should continue to prevent harassment of parties by multiple owners of relatively indistinct patents, except to the extent mandated by the Act.

I suggest that the Interim Rule should be amended so that the relevant portion of §1.321(d) reads as follows:

(4) Include a provision that the owner of the rejected application or patent and the owner of the disqualified patent or application each:

(i) Agree that the rejected application or patent and the disqualified patent or application shall be enforceable only for and during such period that either:

(A) the owner of the rejected application or patent retains such ownership and the owner of the disqualified patent or application retains such ownership; or

(B) the rejected patent or application and the disqualified patent or application are commonly owned; and

(ii) Agree that such agreement shall be binding upon the owner of the rejected application or patent, its successors, or assigns, and the owner of the disqualified patent or application, its successors, or assigns.

It may be that the Office recognizes that the owner of a patent related to a second patent by a terminal disclaimer that refers to a joint research agreement can find itself in the unenviable position that its patent cannot be enforced against a third party on account of a license granted to the third party by the owner of the second patent (and that the third party is therefore unwilling to license its patent). It may also be regrettable that this can occur under the regulations necessary to implement the Act as intended by Congress. Nonetheless, the Office is only authorized to implement the particular form of "common ownership" that Congress has defined in the Act - it does not have the authority to regulate the licensing contracts which patentees may wish to pursue.

Double Patenting

Section 1.109(b) of the Interim Rule sets forth a new basis for rejecting a patent claim, namely that patents and applications that are not commonly owned may be cited against one another in an obviousness-type double-patenting rejection, regardless of whether the owner of either patent or application seeks to invoke the benefits of 35 U.S.C. § 103(c)(2).

It seems more sensible to me that the double patenting provisions of § 1.109(b) should apply only for a joint research agreement that is **disclosed in** the application. If the agreement is not disclosed in the application, then the provisions of 35 U.S.C. § 103(c)(2) do not apply, and any prior art pursuant to 35 U.S.C. § 102(e), (f), or (g) can be cited against the application. The Act does not disqualify from patentability subject matter that may have been invented by parties to a joint research agreement, and the Office has no authority to limit the scope of patentable subject matter in the absence of a grant of such authority by Congress or a corresponding interpretation of current law by a court of competent jurisdiction.

I suggest that the first sentence of Interim Rule §1.109(b) should be amended to read as follows:

*(b) A double patenting rejection will be made in an application or patent under reexamination if the application or patent under reexamination claims an invention that is not patentably distinct from an invention claimed in a non-commonly owned patent by or on behalf of parties to a joint research agreement **disclosed in the application or patent under reexamination** 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.*

Recordation of Joint Research Agreements

Section 1.71(g)(1) of the Interim Rule provides that, if the specification of a patent application discloses the names of the parties to a joint research agreement as provided in 35 U.S.C. § 103(c)(2)(C), then "*the specification must also provide or be amended to provide the following information, or the location where (i.e., by reel and frame number) such information is recorded in the assignment records of the Office.*" This requirement seems to me to be beyond an appropriate scope of inquiry for the Office. 35 U.S.C. § 03(c)(2)(C) requires that the specification disclose only the names of the parties to the joint research agreement.

The requirement in the rule (§ 1.71(g)(1)(i)) that the date the agreement was executed may be prove to be more difficult to comply with than the Office anticipates. Joint or cooperative research arrangements are often subject to numerous agreements, each of which may be executed on different dates by the individuals signing the agreements. Furthermore, the agreements may have various "effective," "beginning," "executed," or other dates defined by the provisions of the agreement. In view of i) the duties of candor and good faith owed to the Office by applicants, practitioners, and others, ii) the availability of patent unenforceability as a defense should those duties be ignored, and iii) the impracticality of the Office confirming any date offered by an applicant, there appears to be no useful purpose served by requiring that the date of execution of the agreement be listed in the specification.

There also appears to be no reason to require applicants who have not already done so to include a "*concise statement of the field of the claimed invention*" (§ 1.71(g)(1)(ii)) in the application. Such information appears to be more accurately reflected in the actual claims in the application. To the extent that this requirement was intended to be directed to a statement of the field of investigation in a joint research agreement, such a requirement does not appear in the Interim Rule, and is as equally unverifiable by the Office as the execution date of the agreement.

I suggest that the word "must" in Interim Rule §1.71(g)(1) should be deleted and the word "may" should be substituted in its place.

Please consider the comments made in this letter upon reconsideration of the Interim Rule. Please do not hesitate to contact me if I can better explain any issue raised in this letter, or if I can be of assistance in any other way.

Very truly yours,

Gary D. Colby
Reg. No. 40,961