



Brian P. Barrett
Patent Counsel

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
Phone 317-276-7243
Fax 317-276-5172

E-mail: barrettbp@lilly.com

February 8, 2005

Box Comments-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA, 22313-1450

Attention: Mr. Robert A. Clarke

**Re: Comments Regarding Changes To Implement the Cooperative Research and
Technology Enhancement Act of 2004 Interim Rule;
70 Federal Register 1818 (January 11, 2005)**

Dear Mr. Clarke:

The following are the comments of Eli Lilly and Company (Lilly) with respect to the Interim rule (Rule) to implement the Cooperative Research and Technology Enhancement Act of 2004 (Act). Lilly appreciates the opportunity to provide its comments on the Rule.

COMMENTS

Lilly commends the U.S. Patent and Trademark Office (PTO) for publishing this Rule so promptly. The Rule was necessary because the Act applies to patents granted on or after December 10, 2004 and, particularly, to address the double patenting and terminal disclaimer requirements resulting from the Act. Following are general comments regarding the double patenting and terminal disclaimer requirements necessitated by the Act and comments specific to certain sections of the Rule. Specific amendments to the Rule are also suggested.

Double patenting and terminal disclaimer requirements: The Rule appropriately recognizes the need to apply double patenting principles to prevent separate actions for enforcement of more than one patent with claims that are not patentably distinct. Because the Act permits patents with patentably indistinct claims to be separately owned, the Rule also complies with the intent of Congress by requiring all owners of all involved patents, i.e., the owner of the patentably indistinct patents as well as any owners of any first-issued patents against which the disclaimer is made, to execute a terminal disclaimer to obviate a double patenting rejection. The Rule

further recognizes that absent this requirement, the right to separately enforce the first-issued patent apart from the patentably indistinct patent cannot be avoided.

Section 1.71 Detailed description and specification of the invention: Section 1.71(g)(1)(i) (and Sections 1.311 and 1.331) requires the date the joint research agreement was executed, presumably to assist the PTO in determining whether the requirements of 35 U.S.C. §103(c)(2) are satisfied.

A joint research agreement under 35 U.S.C. §103(c)(3) may or may not be effective on the execution date. Section 1.71(g)(1)(i) and other sections requiring the execution date (Sections 1.311 and 1.331) should be amended to require providing the effective date of the joint research agreement. The effective date of the joint research agreement will better assist the PTO in determining compliance with the requirements set forth in 35 U.S.C. §103(c)(2).

Section 1.109 Double patenting: This section indicates when an obvious-type double patenting rejection will be made and that a double patenting objection may be obviated by filing a terminal disclaimer in accordance with §1.321(c) for commonly owned inventions and §1.321(d) for non-commonly owned inventions. Lilly requests three changes to this section.

1. Section 1.109 (a) and (b) should be amended in accordance with §1.321 to reflect that a double patenting rejection may be based upon a patent application.

A double patenting rejection in a patent application or a patent in a reexamination proceeding may be based upon an issued U.S. patent (disqualified patent) or a co-pending U.S. patent application (disqualified patent application). Although §1.321 provides that a double patenting rejection may be based on both a patent and a patent application, §1.109(a) and (b) only identify a patent as a basis for a double patenting rejection. Therefore, §1.109(a) and (b) should be amended in accordance with §1.321 to reflect that a double patenting rejection may also be based upon a patent application.

2. Section 1.109 needs amended to clarify that a double patenting rejection will be made in an application or a patent under reexamination that claims an invention that is not patentably distinct from an invention claimed in a non-commonly owned patent or application by or on behalf of parties to a joint research only if there is compliance with the requirements set forth in 35 U.S.C. §103(c)(2)(C) of the Act and §1.71(g) of the Rule.

The parties to a joint research agreement may chose not to invoke the “safe harbor” provisions of 35 U.S.C. §103(c), as amended by the CREATE Act, for example, by not complying with the requirements set forth in 35 U.S.C. §103(c)(2)(C) and §1.71(g). Current §1.109 is subject to a much broader interpretation that would require a double patenting rejection in situations involving inventions that are not commonly owned, are not patentably distinct and that are not subject to the “safe harbor” provisions of the Act. Therefore, §1.109 should be amended to clarify that a double patenting rejection will not be made in an application or patent under

reexamination for non-commonly owned inventions not subject to the “safe harbor” provisions of the Act.

3. Section 1.109 should be clarified such that the double patenting rejection for commonly owned and separately owned patents and applications are addressed in different paragraphs. One way to accomplish this objective is to eliminate the following sentence from §1.109(a) and (b):

“This double patenting rejection will be made regardless of whether the application or patent under reexamination and the commonly owned patent have the same or a different inventive entity.”

Eliminating this sentence will clarify §1.109 because immediately following this sentence in §1.109(a) and in §1.109(b) is a reference to two different types of terminal disclaimers – a terminal disclaimer filed in accordance with §1.321(c) and a terminal disclaimer filed in accordance with or §1.321(d). The appropriate terminal disclaimer is dependent on whether the disclaimer is filed to obviate a double patenting rejection of a commonly owned patent or application (§1.321(c)) or to obviate a double patenting rejection of a non-commonly owned patent or application (§1.321(d)). Deleting the quoted sentence will clarify the Rule by referencing the appropriate terminal disclaimer in the paragraph will the corresponding double patenting-rejection that based on commonly owned (§1.109(a)/§1.321(c)) and non-commonly owned (§1.109(b)/§1.321(d)) inventions.

Section 1.321 Statutory disclaimers, including terminal disclaimers: This section provides the requirements for a terminal disclaimer in an application or patent in a reexamination to obviate a double patenting rejection based upon a non-commonly owned patent or patent application. Lilly suggests three changes to this section.

1. This Section should be clarified to indicate that a patent or patent application that is disqualified under 35 U.S.C. §103(c) is disqualified only after compliance with the requirements in 35 U.S.C. §103(c)(2)(C) of the Act or §1.71(g) of the Rule, not merely because an invention results from activities undertaken within the scope of a joint research agreement. One way to accomplish this result is to insert “under §1.109(b)” between “rejection” and “based” in §1.321(d).

2. A terminal disclaimer filed to obviate a judicially created double patenting rejection (§1.321(c)) must include a statement by the applicant or assignee that includes the extent ownership interest in the patent to be granted. The PTO relies on this statement in determining whether the requisite “common ownership” exists to satisfy the requirements of what is now 35 U.S.C. §103(c)(1). Joint research agreement parties should also be required to include a statement that the PTO can rely on to determine compliance with 35 U.S.C. §103(c)(2). The amendment below suggests certain language to accomplish this objective.

3. The Rule provides no means for the public to determine that a disqualified patent or disqualified application is subject to the restrictions in accordance with the terminal disclaimer filed in the rejected application or the rejected patent. There are several ways the PTO can ensure the necessary public notice. The PTO could require either the owner of the disqualified patent or disqualified application or the owner of the rejected application or rejected patent to file a copy of the terminal disclaimer in the file history of the rejected application or rejected patent; the PTO could require the owner of the rejected application or rejected patent provide an extra copy of the terminal disclaimer, and the PTO could include it in the file history of the rejected application or rejected patent; the PTO could create a database maintaining the relevant information, etc. It is important that the PTO provide a means for the public to determine that a disqualified patent or disqualified application is subject to the requirements as stated in the signed terminal disclaimer.

Section 3.11 Documents which will be recorded: This section provides an opportunity to satisfy the requirements of 35 U.S.C. §103(c)(2) by recording a joint research agreement or an excerpt of a joint research agreement in the assignment records of the PTO pursuant to §1.71(g)(1). This section should be clearer that recording is not required and a specific reference to §1.71(g)(1) may assist in finding the applicable section of the Rule.

Certain specific amendments to the Rule are suggested on the next page (underline indicates suggested additions and brackets indicate suggested deletions).

Thank you again for the opportunity to provide comments on the Rule.

Sincerely,



Brian P. Barrett
Patent Counsel

Section 1.109 Double patenting.

(a) 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 commonly owned patent or application. [This double patenting rejection will be made regardless of whether the application or patent under reexamination and the commonly owned patent have the same or a different inventive entity.] A judicially created double patenting rejection may be obviated by filing a terminal disclaimer in accordance with Sec.1.321(c).

(b) A double patenting rejection will be made in an application or patent under reexamination meeting the requirements set forth in §1.17(g) 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 or application by or on behalf of parties to a joint research agreement. [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 Sec. 1.321(d).

Section 1.321 Statutory disclaimers, including terminal disclaimers.

* * * * *

(d) A terminal disclaimer, when filed in a patent application (rejected application) or a patent in a reexamination proceeding (rejected patent) to obviate a double patenting rejection under §1.109(b) based upon a patent (disqualified patent) or application (disqualified application) that is not commonly owned but was disqualified under 35 U.S.C. §103(c) as resulting from activities undertaken within the scope of a joint research agreement, must:

(1) Comply with the provisions of paragraphs (b)(2) through (b)(4) of this section;

(2) Include a statement that the invention claimed in the rejected application or rejected patent 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 as required by 35 U.S.C. §103(c)(2)(A) and that the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement as required by 35 U.S.C. §103(c)(2)(B);

[(2)] (3) Be signed in accordance with paragraph (b)(1) of this section if filed in a patent application or be signed in accordance with paragraph (a)(1) of this section if filed in a reexamination proceeding;

[(3)] (4) Be signed by the patentee or by the applicant, or an attorney or agent of record, of the disqualified patent or disqualified application; and

[(4)] (5) Include a provision that the owner of the rejected application

or rejected patent and the owner of the disqualified patent or disqualified application each:

(i) Waive the right to separately enforce and the right to separately license the rejected application or rejected patent and the disqualified patent or disqualified application;

(ii) Agree that the rejected application or rejected patent and the disqualified patent or disqualified application shall be enforceable only for and during such period that the rejected patent or rejected application and the disqualified patent or disqualified application are not separately enforced and are not separately licensed; and

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

Section 3.11 Documents which will be recorded.

* * * * *

(c) A joint research agreement or an excerpt of a joint research agreement [will] may also be recorded as provided in §1.71(g)(1) [this part]. A joint research agreement or excerpt of a joint research agreement submitted for recording by the Office must include the name of each party to the joint research agreement, the date the joint research agreement was executed, and a concise statement of the field of invention.