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Mr. Robert A. Clarke
United States Patent and Trademark Office
Box Comments-Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

RE: Comments of Genentech in Response to 70 FR 1818 (Changes to Implement the Cooperative Research and Technology Enhancement Act of 2004)

Dear Sir,

The undersigned provides, herewith, the comments of Genentech, Inc. on the above-referenced solicitation of public comment.

Genentech, founded in 1976, is a biotechnology company that develops biologics and drugs to meet unmet medical needs. Genentech actively pursues patent protection for its innovations, and respects the intellectual property of others. Genentech frequently partners with other entities to conduct research and development, and supports efforts to ensure that the fruits of such collaborations can be effectively protected through patents.

Genentech was a strong supporter of legislation to address the challenges facing collaborative research ventures. These challenges included in particular problems that ensued from the interpretation of the law governing anticipation and obviousness expressed by the Federal Circuit in the 1997 decision of *Oddzon v. Just Toys, Inc*., 43 USPQ2d 1641, 1646 (Fed. Cir. 1997). The CREATE Act makes it possible for parties engaged in certain collaborative research to take steps to mitigate the risks created by the *Oddzon* decision. The success of implementation of the CREATE Act will be measured by the ease with which collaborative entities can claim the benefits of the legislation, while ensuring that the interests of the public identified in the legislation are protected.

General Observations

Genentech believes the rule package, in general, is consistent with the goals and requirements of the legislation. However, the rule package appears to impose a number of

conditions as to form that are not required by the legislation, and which could operate to impede the objectives of the legislation.

The amendments to title 35 enacted through the CREATE Act impose three requirements on patent applicants seeking to rely upon the exemption created by the Act; namely:

(i) that the invention was made by or on behalf of the parties to a joint research agreement after the collaboration was established between the collaborators (35 U.S.C. 103(c)(2)(A));

(ii) that the claimed invention was made as a result of actions taken under the joint research agreement (§103(c)(2)(B)); and

(iii) that the public is given notice through the listing of the names of the collaborators in the application. (§103(c)(2)(C)).

In addition, the CREATE Act, through its legislative history, makes it clear that the law governing obviousness-type double patenting is to be applied, *mutatis mutandis*, to situations of double-patenting that can arise by operation of the law (i.e., where earlier-issued patents owned by one or both of the collaborators contain claims that render obvious claims in a pending application).

Section 103(c)(2) allows a patent applicant to disqualify prior art under §102(e), (f) or (g) once the Office has found that the prior art renders a claim *prima facie* obvious under §103(a). This simple observation is a crucially important predicate for the rules that the PTO can and should adopt. Specifically, §103(c)(2) situations can arise only after the PTO has made a determination that a pending claim is *prima facie* obvious within the meaning of §103(a). If this predicate is not established, §103(c)(2) is not implicated. Even when a claim has been rejected under §103(a), an applicant may elect to contest the determination by the Office, as by traversal, rather than invoke §103(c)(2), even if that applicant is entitled to do so.

Disclosure or other requirements related to the CREATE Act therefore should be imposed by the Office only in situations where §103(c)(2) is invoked by an applicant. In particular, requirements should be imposed only on those applicants that rely on §103(c)(2) to overcome a rejection under §103(a) of one or more claims in the application. Given the flexibility provided in the statute to permit parties to amend their applications to add information that enables that applicant to qualify for the benefits of the Act, it would be inappropriate for the PTO to attempt to impose requirements on all applicants, regardless of whether §103(c)(2) is implicated. The Office accordingly should (i) make disclosures related to the CREATE Act conditional on the election by the applicant to invoke this authority, and (ii) not impose disclosure obligations on applicants in a general manner.

The nature of information requirements imposed an applicant seeking to invoke §103(c)(2) also should be tailored specifically to what is required by the CREATE Act. Substantively, an applicant is entitled to invoke §103(c)(2) to overcome a rejection of a claim by the Office as being obvious under §103(a) by establishing that:

(i) the names of the collaborators appear in the application;

(ii) the invention (i.e., the subject matter of the claims being rejected) arose out of actions undertaken pursuant to a joint research agreement;

(iii) the invention was made after the joint research agreement was established; and,

where the prior art being relied upon is an earlier issued patent owned by one or more of the parties to the joint research agreement, by providing:

(iv) a terminal disclaimer that will prevent the separate enforcement of the patent benefiting from the operation of §103(c)(2) relative to the earlier issued patent.

An applicant should be able to establish items (ii) and (iii) through the provision of a suitable representation to the Office; namely, that the invention arose out of actions undertaken pursuant to a joint research agreement, and that the invention was made on a date after the date the joint research agreement was established. Genentech notes that such representations when made to the Office for the purpose of relying on §103(c)(2) to overcome a rejection under §103(a) would be subject to the duty of disclosure under 37 CFR §1.56 and the general oath requirements in a sworn statement. Given this, the PTO should not impose excessive information requirements, such as requiring submission of copies of the actual agreements, precise characterizations of the agreements, or overly detailed descriptions of invention dates.

In view of these observations, Genentech submits that the present regulations must be revised so as to take a form that is more consistent with the legislative intent; namely, to permit eligible applicants to optionally invoke the safe harbor of §103(c)(2) once the Office has rejected claims under §103(a) and to require submission of only such information that is necessary to establish an applicant is entitled to invoke §103(c)(2). While acknowledging that the Office is justified in demanding certain information and representations from an applicant seeking to invoke §103(c)(2), Genentech believes the Office should permit an applicant to satisfy these information requirements by making appropriate representations by filing a declaration (or equivalent sworn statement) that provides the necessary information and representations to enable the Office to confirm that the applicant is entitled to invoke §103(c)(2). Genentech believes that a declaration or comparable statement would be a more appropriate mechanism for explaining the nature of a joint research agreement, particularly when the joint research agreement is established by multiple writings or documents (which is specifically envisioned by the Act).

Thus, Genentech submits that by rule or practice the Office should permit applicants to satisfy the non-statutorily mandated requirements regarding eligibility for invocation of §103(c)(2) through a declaration or statement to accompany an application, rather than through an amendment to the specification to incorporate such information. Changes to Rule 71(g) or another rule are thus necessary, in particular, to delete the requirement that applicants amend their specifications to recite the information specified in paragraphs (i) and (ii) of subsection (g). The Office can also incorporate these information requirements in the new terminal disclaimer requirement being established by 37 CFR 1.321(d).

Observations on Specific Rules

1. Proposed Rule 1.71(g)

Genentech submits that proposed rule 37 CFR §1.71(g)(1) is overbroad in two key respects.

First, the legislation makes it abundantly clear that a patent applicant must disclose the names of the collaborating parties in the application. Yet, despite this, Rule 71(g)(1) appears to require that the applicant amend the specification to recite certain information. An applicant, under the law, should be permitted to provide the names of parties to a joint research agreement through means other than through an amendment to the specification. For example, an applicant should be authorized to identify the parties through a suitable notice that is recorded with the assignment records of the patent, through a submission of a statement in the file wrapper of the application to establish eligibility to claim §103(c)(2) or through other records that form part of the patent file wrapper and become part of the public record. In fact, in situations where the Office demands submission of a terminal disclaimer, the terminal disclaimer can itself serve the necessary function of disclosing the names of the collaborators to the public. Since the public is able to obtain access to the full file wrapper and application records associated with any patent, and since the goal of §103(c)(2)(C) is to provide public notice of the names of collaborators, the PTO should amend proposed rule 71(g)(1) to permit applicants to satisfy the requirements of §103(c)(2)(C) through means other than a disclosure in or amendments to the specification.

The legislation also does not demand that information beyond the names of the collaborators be included in the application outside the specific situation where an applicant wishes to overcome a rejection for obvious-type double patenting over the claims of another patent, as noted above. Thus, the only instance where information beyond the names of collaborators must be provided to the PTO is where the PTO has imposed such a rejection and the applicant elects to invoke §103(c)(2) to overcome that rejection. In that setting, the Office is justified in demanding not only the names of the collaborators but such additional information and assurances as needed to determine that the Applicant may properly invoke §103(c)(2) (i.e., the date of the agreement, a representation that the invention arose from activities undertaken within the scope of the joint research agreement, and an appropriate terminal disclaimer). Accordingly, Genentech submits that Rule 71(g)(1) should be amended to not require applicants to make amendments to provide the information specified in Rule 71(g)(1)(i) and (ii).

2. Proposed Rule 1.321

Genentech agrees with the Office that a new form of terminal disclaimer is appropriate to establish by rule to implement the CREATE Act. The elements and form of such terminal disclaimers as set forth in the proposed rule are generally consistent with the requirements of the Act with one important exception. Under proposed rule 1.321(d)(3) and (4), the owner of a "disqualified" patent is required to sign a terminal disclaimer executed by and intended for the application being rejected over the disqualified patent. The standard being proposed will create immense practical difficulties and is unnecessary to give effect to the requirements of the Act.

The legislative history of the CREATE Act makes clear that the Office is to require the submission of a terminal disclaimer in the specific situation where an earlier issued patent owned by one of the parties to a joint research agreement contains claims that render obvious (under obvious-type double patenting standards) the claims in an application, and the applicant wishes to overcome a rejection for double-patenting in that application. In that situation, an applicant may invoke §103(c)(2), and provide a terminal disclaimer to the Office. The requirements of the disclaimer are to ensure that the patents at issue (the earlier granted and that which will issue from the application being rejected) expire on the same date. In addition, the terminal disclaimer must make separate enforcement of the patents impossible.

In this latter respect, Genentech observes that the requirements of the CREATE Act can readily be met by structuring a terminal disclaimer to be filed in the application being rejected so as to preclude the separate enforcement or licensing of that patent relative to the disqualified patent without having the owner of the disqualified patent also execute such a disclaimer. In other words, there is no need to independently encumber the earlier issued patent or earlier patent owner. A terminal disclaimer that precludes separate enforcement of the patent issuing from the rejected application relative to the disqualified patent will bind the entity with legal authority to control enforcement of the later issuing patent. If that patent owner attempts to separately enforce the patent, the terms of the disclaimer are violated and the patent is invalid. If the later issuing patent is enforced before the earlier issuing patent, any subsequent and independent enforcement under the earlier issuing patent will conflict with the terms of the terminal disclaimer and will void the later issuing patent. Since the protections mandated by the Act can thus be effectively implemented without the necessity of separately encumbering the earlier issued patent or patent owner, the rules should be restructured to delete the requirements specified in sections 37 CFR 1.321(d)(3) and(4) that are to be imposed on the owner of the disqualified patent.

Accordingly, Genentech urges the PTO to restructure the requirements of proposed Rule 1.321(d) to impose requirements on the owner of the application that is seeking to obtain the benefit of §103(c)(2), and to not impose formal requirements (including signatures) from the owner of the "disqualified" patent.

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Genentech supports the efforts of the Office to provide a good faith implementation of the CREATE Act, and respectfully urges the Office to make changes to the proposed Rules consistent with the above comments.

Sincerely,

Jeffrey P. Kushan