Keywords: **35 U.S.C. § 303(a); reexamination; substantial new question of patentability; considered for a substantially different purpose**

General: **For purposes of reexamination, a reference may raise a substantial new question of patentability even after the reference has been considered by a court in determining validity and by the PTO as a secondary reference in a prior examination.**

In re Swanson
540 F.3d 1368, 88 U.S.P.Q.2d 1196 (Fed. Cir. 2008)
Decided September 4, 2008

I. Facts

The claim at issue (claim 22 of U.S. Patent No. 5,073,484) relates generally to a test strip that includes multiple reaction zones. Each reaction zone includes imbedded reactants configured to detect the presence of an analyte. A test solution is applied to one end of the strip and flows through the reaction zones as it approaches the other end. An indicator within each reaction zone indicates the presence of various compounds.

During prosecution, the examiner rejected a dependent claim under § 103 as being unpatentable over various references "in further view of any one of Ruhenstroth-Bauer et al., Brown et al. and Deutsch et al." The examiner contended that Deutsch, and the other cited references, taught a "specific ligand-antiligand binding pair." This was the only reference the examiner made to Deutsch during prosecution. The subject matter of this dependent claim was added to independent claim 22 during prosecution.

After the '484 patent issued, Abbott, the exclusive licensee, sued Syntron for patent infringement. Syntron counterclaimed, claiming invalidity of claim 22. Specifically, Syntron claimed that Deutsch taught flowing a solution along a medium. The district court found that "Syntron had failed to prove by clear and convincing evidence that the claims were anticipated, obvious, or otherwise invalid." The Federal Circuit affirmed, holding that "the jury could have reasonably interpreted the language of the claims standing alone, as requiring that the solution itself provide the required flow."

Syntron then requested an ex parte reexamination of the '484 patent. The examiner rejected claim 22 as being anticipated by Deutsch. The Board affirmed the examiner's rejection, and explained that "claim 22 does not contain a limitation requiring that the test solution itself provide the flow." The Board also found that a substantial new question of patentability was raised because Deutsch was considered for a different purpose during the initial examination.

II. Issues

A. Does a court's consideration of a reference in determining the validity of a patent necessarily preclude the reference from raising a substantial new question of patentability in a subsequent reexamination?

B. Does an examiner's consideration of a reference during a prior examination necessarily preclude the reference from raising a substantial new question of patentability in a subsequent reexamination?

III. Holdings

A. No. The language and legislative history of 35 U.S.C. § 303, along with the differences between civil litigation and prosecution, demonstrate that Congress did not intend a prior court judgment

upholding the validity of a claim to prevent the PTO from finding a substantial new question of patentability.

B. No. During reexamination, if a reference is considered for a "substantially different purpose" than a prior examination, the reference may raise a substantial new question of patentability.

IV. Discussion

According to 35 U.S.C. § 303(a), the PTO may only grant a reexamination request if the request raises a "substantial new question of patentability." In 2002, Congress amended 35 U.S.C. § 303(a) to specifically overturn a Federal Circuit case holding that "prior art previously considered by the PTO in relation to the same or broader claims" cannot raise a substantial new question of patentability. Currently, 35 U.S.C. § 303(a) states, "Within three months following the filing of a request for reexamination under the provisions of section 302 of this title, the Director will determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request. . . . **The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.**" The legislative history further explains, "the appropriate test to determine whether a substantial new question of patentability exists should not merely look at the number of references or whether they were previously considered or cited but their combination in the appropriate context of a new light as it bears on the question of the validity of the patent."

A. First, it is important to note that the issue presented during the invalidity suit and the issue raised by the examiner during reexamination are the same, "whether Deutsch satisfies the flowing limitation of the asserted claims, and thus, anticipates them."

The Federal Circuit found that neither the statute itself, nor the legislative history, precludes raising a substantial new question of patentability based on a reference considered during litigation. The court also noted that different evidentiary standards between reexamination and litigation could result in different conclusions regarding validity. "In civil litigation, a challenger who attacks the validity of patent claims must overcome the presumption of validity with clear and convincing evidence that the patent is invalid." In contrast, "[i]n PTO examinations and reexaminations, the standard of proof – a preponderance of the evidence – is substantially lower than in a civil case." Furthermore, during prosecution, claims are to be given "their broadest reasonable interpretation, consistent with the specification." Because a substantial new question of patentability is "a question which has never been considered by the PTO" and the anticipation of claim 22 by Deutsch under the preponderance of the evidence standard has never been considered, a substantial new question of patentability has been raised in this case.

B. Based on the amended 35 U.S.C. § 303(a), the Federal Circuit found that "a reference may present a substantial new question even if the examiner considered or cited a reference for one purpose in earlier proceedings." However, the question of patentability presented by the reference in reexamination must not have previously been evaluated by the PTO. "The substantial new question requirement 'guards against simply repeating the prior examination on the same issues and arguments' and bars 'a second examination, on the identical ground that had previously been raised and overcome.'" The test is whether the reference is considered for a "substantially different purpose" during reexamination.

In the present case, the examiner only considered Deutsch for the purpose of teaching a "specific ligand-antiligand binding pair" during the initial examination. During reexamination, Deutsch was considered for teaching flowing a solution along a medium. Therefore, the reference was considered

for a "substantially different purpose" during reexamination. As a result, Deutsch raises a substantial new question of patentability.

V. Conclusion

For purposes of reexamination, a reference may raise a substantial new question of patentability even if the reference was considered by a court in determining validity. A reference may also raise a substantial new question of patentability even if the reference was considered during a prior examination if the reference was considered for a "substantially different purpose."