

In re Swanson: Ex Parte Reexamination in the Patent Office Provides Second Chance to Invalidate Patent

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It may not literally keep in-house attorneys up at night, but the chance that a relevant patent owned by another may unexpectedly show up on one's desk in the morning is certainly not a pleasant thought. In addition to being a distraction from the main business, none of the options in this scenario are very satisfying. One option is to do nothing — while possibly obtaining an opinion letter to shield from enhanced damages — and hope that the patent owner will not enforce the patent. But failing to address a potentially troublesome patent may put a cloud of risk over the business, possibly affecting the business's valuation and flagging a diligence issue for potential investors or acquirers in the future.

Other options include designing around the patent or obtaining a license or ownership interest in the patent; however, technical or financial factors often limit these solutions. In many circumstances, the only recourse of a business that is threatened by a patent is to bring a legal proceeding to resolve the uncertainty caused by the patent. But litigating patent validity or infringement issues in District Court is an expensive option. To provide a less expensive quality check on issued patents, Congress created the ex parte reexamination, a useful post-grant procedure for addressing the validity of a suspect patent in the U.S. Patent and Trademark Office instead of in court.

Reexamination and the “Substantial New Question of Patentability” Requirement

Any person can initiate an ex parte reexamination by filing a request for reexamination of a patent based on one or more prior art publications. The Patent and Trademark Office evaluates the request and grants the request only if it determines that “a substantial new question of patentability affecting any claim of the patent concerned is raised by the request.” 35 U.S.C. § 303(a). This “substantial new question of patentability” requirement is designed to balance the need to protect patent owners from harassment by third parties while still enabling the public access to an important tool to remove bad patents from the intellectual property landscape.

The reexamination statute was initially construed in a way that applied the substantial new question of patentability requirement in a very strict bright-line manner. Specifically, in *In re Portola Packaging Inc.*, 110 F.3d 786 (Fed. Cir. 1997), the Court of Appeals for the Federal Circuit interpreted the requirement to preclude reexamination based on “prior art

previously considered by the Patent and Trademark Office in relation to the same or broader claims.” This effectively barred any reexamination based on a printed publication that was considered during the patent's initial examination, regardless of how the reference had been considered.

Congress disagreed with *Portola Packaging's* bright-line rule and, in 2002, amended § 303(a) to conclude with the following sentence: “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.” In so doing, Congress specifically stated that the amendment “overturns the holding of *In re Portola Packaging Inc.*” Rather than a strict prohibition against reexamination of a patent based on a publication that had been considered during the initial examination of a patent, Congress explained that “the appropriate test . . . 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.” Until recently, the Federal Circuit has not had the opportunity to evaluate the scope of the substantial new question of patentability requirement since Congress amended § 303(a) in 2002. This changed with *In re Swanson*, ___ F.3d ___ (Fed. Cir. 2008).

History of the Swanson Patent

Melvin Swanson and Patrick Guire filed an application for the patent at issue in 1983. Titled “Quantitative Analysis Apparatus and Method,” the patent application generally covered a method of analyzing small amounts of biological solutions to detect the presence of a particular substance in the solution. The application included a claim to a method that comprised the steps of providing an immobilized reactant in a flow path, flowing a test solution over the reactant and detecting the presence of a substance in the test solution based on the interaction between the test solution and the reactant. The patent application also included dependent claims that refined this method claim, one of which covered a specific type of reaction, an immunoreaction, to detect the substance.

About a year after the application was filed, the patent examiner rejected the claims in the application under various combinations of prior art publications. One of the publications used in the rejection was U.S. Patent No. 4,094,647, issued to Deutsch et al., which disclosed

a method of detecting ligand-antiligand binding pairs to determine the presence of a ligand in a biological fluid sample. In the rejections, however, Deutsch was cited as a secondary reference, used only for its disclosure of the immunoreaction feature recited in the dependent claim. Importantly, the examiner never asserted that Deutsch disclosed the main steps in the claim. The applicants amended the claims in response to the rejection, and the patent issued on Dec. 17, 1991, as U.S. Patent No. 5,073,484. The inventors assigned the patent to Surmodics, Inc., which exclusively licensed the patent to Abbott Laboratories.

In December 1998, Abbott sued Syntron Bioresearch, Inc. for infringement of the '484 patent. Among the counterclaims brought by Syntron was a claim that the patent was invalid as anticipated by the Deutsch reference. The jury in that case returned a verdict that Deutsch did not anticipate the claims. In reaching this verdict, the jury reasoned that the claims of the '484 patent required that the test solution provide the claimed flow, a feature that was not disclosed in Deutsch. The Federal Circuit affirmed this part of the jury's verdict as supported by substantial evidence.

Syntron then filed a request for an ex parte reexamination of the '484 patent, in part, asserting a substantial new question of patentability based on Deutsch. The examiner granted the request and ultimately rejected the claims, and the Board of Patent Appeals and Interferences affirmed this rejection in *In re Swanson*, No. 05-0725, Reexamination No. 90/006,785 (B.P.A.I. 2007). Abbott argued that Deutsch could not be the basis of a substantial new question of patentability because Deutsch had been considered by the patent examiner during examination, by a jury during a trial, and by the Federal Circuit itself during the appeal.

The Federal Circuit rejected these arguments and found that Syntron's request for reexamination did present a substantial new question of patentability based on Deutsch. The court first rejected Abbott's request to adopt a bright-line rule that would preclude a reexamination based solely on references used in a rejection of claims during the original examination of a patent. Refusing to do so, the court reiterated that the issue is whether the same question of patentability had been earlier considered, not whether the particular reference had been.

The court also rejected Abbott's argument that the previous consideration of Deutsch by both the District Court and the Federal Circuit precluded a new question of patentability. In so doing, the court held: "As properly interpreted a 'substantial new question of patentability' refers to a question which has never been considered by the PTO; thus, a substantial new question can exist even if a federal court previously considered the question." Therefore, the court found that the reexamination was not improper and affirmed the final rejection of the patent claims.

Second Bite at the Invalidity Appeal

It may at first appear to be an inherent conflict to find a substantial new question of patentability based on a reference that a district court has already reviewed. However, this can be resolved by noting the difference between these two forums. In a District Court, and unlike in the Patent and Trademark Office, a patent enjoys a presumption of validity, and a clear and convincing standard of proof is required to invalidate a patent, not a mere preponderance of the evidence. Also, claims may be construed more broadly in the Patent and Trademark Office, as they are given their "their broadest reasonable interpretation, consistent with the specification," during examination to avoid issuance of an overly broad patent. In fact, during reexamination the Patent and Trademark Office is not bound by a District Court's claim construction. *In re Trans Texas Holdings Corp.*, 498 F.3d 1290 (Fed. Cir. 2007).

Accordingly, the take-home message of *In re Swanson* is that losing an invalidity battle at trial is not necessarily final. In many cases, reexamination may offer a litigant a second chance to attack a patent's validity — once in court and another time in the Patent and Trademark Office. The reexamination strategy in view of previously considered prior art is particularly viable after the loosening of the obviousness test by *KSR International Co. v. Teleflex Inc.*, 550 U.S. 127 (2007). Moreover, the recent statistics on ex parte reexamination reported by the Patent and Trademark Office in June 2008 make the reexamination option even more attractive. The Patent and Trademark Office grants over 90 percent of requests for ex parte reexamination, and of those, 75 percent of the patents have all claims canceled or at least some of the claims narrowed.

Accordingly, anyone concerned by a potentially troublesome patent should be encouraged to look for new questions of patentability to request reexamination of the patent. Even if a prior art reference has already been considered, there may be a number of different, more persuasive ways to present the reference, and ultimately kill the patent.

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