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If at First you won't Succeed, it may not be "Obvious to Try"

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In *Teva Pharmaceuticals, LLC v. Corcept Therapeutics, Inc.*, Docket No. 21-1360 (Fed. Cir. 2021), the Federal Circuit articulated a strict standard for when an invention may be considered invalid for being "obvious to try," thus strengthening certain patents. Under the court's ruling, in order for a patent to be declared invalid, not only must a patent have been obvious to try from several choices with a reasonably expectation of success, but the precise scope of the invention claimed in the patent must have been reasonably expected to have succeeded.

In *Teva*, generic drug manufacturer Teva Pharmaceuticals sought to invalidate a patent covering a method of treating Cushing's syndrome, and attempted to do so under the "obvious to try" standard. Under the "obvious to try" standard, a claim for an invention can be considered obvious if a person of ordinary skill would have had good reason to pursue known options within his or her technical grasp, and if pursuing such options leads to the anticipated success, it is likely that the invention (e.g., a novel method) was not of innovation but instead a result of ordinary skill and common sense.

In *Teva*, the covered method called for reducing a typical dose of a drug from 1,200 mg or 900 mg to 600 mg, and combining that dosage with a second drug. Teva argued to the Patent Trial and Appeals Board (PTAB) that it was obvious to administer the two drugs together, and to a drug developer it would have been obvious to try different doses until a safe level was achieved; thus, the patent should be declared invalid.

The PTAB disagreed, determining that Teva would have to prove that it was obvious to try 600 mg, specifically, and that there would have been a reasonable expectation that the 600 mg dose would work.

Teva appealed to the Federal Circuit, arguing that the PTAB applied an incorrect standard. Under the applied standard, Teva argued, the PTAB was essentially requiring that the prior art precisely predict the patented method. The Federal Circuit disagreed, holding that the correct standard was applied by the PTAB and determined that "the reasonable-expectation-of-success analysis must be tied to the scope of the claimed invention." In order to invalidate the patent, the prior art

would have to render obvious the 600 mg dose, specifically, and provide a reasonable expectation that the 600 mg dose would be effective. The standard did not require that the method would be certain of success, since "absolute predictability is not required."

Having failed to meet the invalidity standard, Teva Pharmaceuticals' patent challenge failed, and US Patent No. 10,195,214 remains active and enforceable.

PRACTICE NOTE

The Federal Circuit's opinion provides increased clarity as to when a patent may be considered obvious to try, and is likely to embolden patent applicants who may have earlier feared invalidity challenges. The ruling may make certain patents more difficult to challenge, so companies relying on trade secret protection for proprietary, mission-critical processes may wish to get ahead of the competition and file for patent protection to avoid business disruption.