

Obvious-to-Try Lessons from Two Federal Circuit Rulings

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The Federal Circuit's recent rulings in *Hoffmann-La Roche Inc. v. Apotex Inc.*, No. 2013-1128 (April 11, 2014) and *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms. Inc.*, No. 2012-1489 (April 21, 2014) highlight a challenge for practitioners addressing claims of invalidity based on the theory that a combination of prior art would be obvious to try: While the obvious-to-try analysis takes place at the time of invention, secondary considerations of nonobviousness may be relevant no matter when they arise.

In *Roche*, the Federal Circuit found that a combination of the prior art would have been obvious to try, and held the patent obvious under §103, in spite of later-discovered evidence of unexpected results. At the same time, *Sanofi* confirmed that evidence of secondary considerations may be relevant regardless of when they are discovered. Thus, obviousness under an obvious-to-try theory is not necessarily precluded by unexpected results, and indeed, unexpected results must be considered. The question becomes whether, and to what extent, secondary considerations that arise after the date of invention outweigh the obviousness of trying predictable, known solutions at the time of invention.

Practitioners facing potentially contradictory and temporally distant evidence of obvious-to-try and secondary considerations should recognize that the court will weigh the evidence in reaching its conclusion. In their presentation, practitioners should emphasize the weight of the evidence in support of their position such that it may prevail over countervailing evidence. For example, is the pool of finite, predictable solutions so small that, regardless of unanticipated

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benefits, one of skill in the art would have been compelled to combine? Or, on the other hand, perhaps an advantage of the invention was so unexpected and unpredictable that, even in view of a few, known options, the success achieved with combining the prior art would not have been obvious to one of ordinary skill in the art at the time of the invention.

Evidence relating to obviousness — including secondary considerations — may have its genesis at any point in time, i.e., before or after the patent application's filing. For example, evidence of commercial success may take several years to develop while evidence of long felt need would naturally predate the invention. *Knoll Pharm. Co. v. Teva Pharms. USA*, 367 F.3d 1381, 1385 (Fed. Cir. 2004) ("Evidence developed after the patent grant is not excluded from consideration, for understanding of the full range of an invention is not always achieved at the time of filing the patent application."); see also *Genentics Inst. v. Novartis Vaccines*, 655 F.3d 1291, 1307 (Fed. Cir. 2011).

Obvious-to-try as a basis for invalidity was verboten prior to *KSR*. As is well known, however, *KSR* opened the door to obviousness under §103 where "there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). Historically, obvious-to-try evidence was evaluated temporally at the time of invention. See, e.g., *Rolls-Royce PLC v. United Techs. Corp.*, 603 F.3d 1325, 1339 (Fed. Cir. 2010). Recently, in *Roche*, the Federal Circuit weighed evidence from the time of invention supporting an obvious-to-try argument against evidence from after the patent grant supporting unexpected results.

In *Roche*, the Federal Circuit found that later-developed evidence of improved efficacy was insufficient to overcome a prima facie showing of obviousness. A panel of Judges Pauline Newman, Alan Lourie and William Bryson (authored by Judge Bryson, with Judge Newman dissenting) affirmed invalidity under the theory that the combination would have been obvious to try. ("As to the amount of the monthly dose, the court found that the combination of several prior art references suggested a dosage level of about 150 mg per month, or at least indicated that a monthly dose of 150 mg was obvious to try."). In so affirming, the panel was not persuaded by later-discovered evidence that the dosage gave superior results to previous dosage forms:

While the evidence would support a finding of superior efficacy of the 150 mg monthly dose in raising BMD levels, as compared to a 2.5 mg daily dose, that improved efficacy does not rebut the strong showing that the prior art disclosed monthly dosing and that there was a reason to set that dose at 150 mg. The evidence of superior efficacy does nothing to undercut the showing that there was a reasonable expectation of success with the 150 mg monthly dose, even if the level of success may have turned out to be somewhat greater than would have been expected.

The panel found that, while there was in fact superior efficacy, obviousness was sufficiently proven because there existed a reasonable expectation of success at the time of filing.

The *Roche* decision, however, did not displace the long-standing principle that evidence of obviousness may

be relevant regardless of when they appear. Indeed, a week later, in *Sanofi*, the panel of Judges Newman, Richard Linn and Evan Wallach (authored by Judge Newman) confirmed that “patentability may consider all of the characteristics possessed by the claimed invention, whenever those characteristics become manifest” in affirming the nonobviousness of the patent in suit based on later discovered evidence.

In affirming nonobviousness, the panel noted that the jury could have relied on evidence that “persons skilled in the art in 1986 would not have predicted the longer-lasting hypertension control demonstrated by the double-ring structures of quinapril and trandolapril in combination with calcium antagonists” to find that the invention was not obvious to try. The *Sanofi* panel, just like the *Roche* panel, was faced with an obvious-to-try analysis and evidence of unexpected results, yet came to the opposite conclusion.

Taken together, *Roche* and *Sanofi* illustrate that when evaluating all of the evidence pertaining to obviousness, the relative weight of different pieces of obviousness evidence — both for and against — appears to be crucial. Even in the face of unexpected results, a patent may still be invalid under an obvious-to-try theory. The court will balance the weight of the evidence — even though certain evidence may have arisen after the relevant time period for an obvious-to-try analysis — to determine whether the invention is invalid under §103.