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PATENT AND TRADEMARK LAW

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The Power of 'KSR'

In last year's *KSR v. Teleflex*, decision, the Supreme Court criticized and relaxed the U.S. Court of Appeals for the Federal Circuit's "rigid" application of its "teaching, suggestion, or motivation" (TSM) test for obviousness. The Court seemingly stemmed the perceived tide of unworthy obvious patented inventions. (See our Patent and Trademark Column, NYLJ, May 23, 2007, at p. 3).¹

Indeed, since *KSR*, the Federal Circuit's decisions finding in favor of the patent challenger have reportedly increased from 63 percent before *KSR* to 71 percent after *KSR*.²

But has the Supreme Court truly paved the way to easier challenges based on obviousness grounds? Although post-*KSR* decisions signal a gradual shift toward more findings of invalidity on obviousness grounds, *KSR*'s impact may not be as profound as originally thought.

The Federal Circuit

In *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*,³ the Federal Circuit, following *KSR*, rejected the need in the prior art for "a precise teaching directed to the subject matter of the challenged claim."

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Claims 1 and 2 of Aventis' patent were directed to one of five structural configurations (the SSSSS isomer configuration) of the drug ramipril "substantially free of other isomers." Ramipril is an angiotensin-converting enzyme inhibitor (ACE Inhibitor) used to treat high blood pressure. The prior art disclosed the ACE Inhibitor enalapril, whose chemical structure differed from ramipril only in that enalapril lacked a ring structure found in the ramipril compound. The SSS isomer of enalapril was seven hundred times more potent than its SSR isomer. The prior art also disclosed a mixture of ramipril containing its SSSSS and SSSSR isomers.

The district court found that because enalapril and ramipril differed in the configuration of a bridgehead structure, one would not be motivated to purify the SSSSS isomer of ramipril.⁴ The Federal Circuit disagreed. "Requiring an explicit teaching to purify the 5(S) stereoisomer from a mixture in which it is the active ingredient is

precisely the sort of rigid application of the TSM test that was criticized in *KSR*."⁵ Enalapril lacked the bridgehead structure of ramipril, but the SSSSS and SSSSR isomers of ramipril differed in the configuration of a single carbon atom located in a part of the ramipril compound common to the enalapril compound. Therefore, the seven-hundred-fold increase in potency provided sufficient motivation for one to purify the SSSSS isomer of ramipril.

KSR's continued impact is evident in *In Re Translogic Technology Inc.*⁶ The patent concerned electric circuits, called multiplexers, designed to select between signals arriving at one of multiple input lines and to direct the input signal to a single output. A multiplexer with two inputs and one output is called a 2:1 multiplexer. The claims specified multiple, specific 2:1 multiplexers, called transmission gate multiplexers (TGM) connected in series. The Gorai reference taught an electric circuit made up of 2:1 multiplexers connected in series, and the Weste reference taught a TGM circuit. Translogic argued that the cited art did not contain the necessary teaching, suggestion, or motivation to combine Gorai and Weste because Gorai failed to disclose the use of TGMs and Weste did not disclose its TGMs connected in series. The Federal Circuit applied the new, flexible TSM test and found the claims obvious. The court reasoned that "an obviousness analysis 'need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person

of ordinary skill in the art would employ.”⁷ “[I]n *Gorai*, a person of ordinary skill in the art would have solved this design need by ‘pursu[ing] known options within his or her technical grasp.’”⁸

In *Translogic*, the Federal Circuit seemingly retreated from its prior position that “common sense” could not be the basis for a motivation to combine. For instance, in *In Re Lee*, decided prior to *KSR*, the Federal Circuit upheld a finding of obviousness, requiring a “specific hint or suggestion in a particular reference” to support the combination of prior art references.⁹ Lee’s claims were directed to a method for automatically displaying the functions of a video display device and demonstrating to a user how to select and adjust those functions. The Nortrup reference described a television set having displayed menus by which the user could adjust audio and video settings. The Thunderchopper reference described a video game having a demonstration mode. In combining the references, the Examiner reasoned that “both the Nortrup function menu and the Thunderchopper demonstration mode are program features and that the Thunderchopper mode ‘is user-friendly’ and it functions as a tutorial, and that it would have been obvious to combine them.” The Board of Patent Appeals and Interferences (board) upheld the rejections, stating “[t]he conclusion of obviousness may be made from common knowledge and common sense of a person of ordinary skill in the art without any specific hint or suggestion in a particular reference,” a position adopted in *KSR*. The Federal Circuit reversed the board’s decision, stating “[t]he factual inquiry whether to combine references must be thorough and searching.” This seemingly contradicts the “common sense” approach in its post-*KSR*, *Translogic* decision.¹⁰

Patents on Obviousness

Despite *KSR*’s criticism, the Federal Circuit does not seem so eager to invalidate patents on obviousness. For example, it is true that *KSR* overturned the long-stand-

ing principle that a patent claim cannot be proved obvious merely by showing that the combination of elements was ‘obvious to try.’¹¹ “When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions...[i]n that instance the fact that a combination was obvious to try might show that it was obvious under §103.” Despite the Supreme Court’s obvious-to-try standard, the Federal Circuit in *Forest Labs. Inc. v. Ivax Pharms. Inc.*,¹² found not obvious claims to a substantially pure compound containing one of only two possible enantiomers (the S enantiomer). A prior art patent disclosed a mixture (racemic) containing the S and R enantiomers.¹³ The prior art also disclosed three possible methods for separating the S enantiomer, that the racemic mixture was used to treat the same conditions as the S enantiomer, and a purified enantiomer was known in some instances to have a potency twice as great as the racemic mixture. Yet, the claims were found not obvious.

On the other hand, just one month prior to *KSR*, the Federal Circuit found obvious claims to the besylate salt of the compound amlodipine.¹⁴ A prior art patent disclosed that salts of amlodipine could be formed by substituting one of its components with a pharmaceutically acceptable anion. At the time, the FDA approved genus contained 53 anions, including the besylate anion of the claimed compound, a genus significantly larger than the two enantiomers in *Forest Labs*. The Federal Circuit denied Apotex’s petition for a rehearing soon after the decision in *KSR*.¹⁵

While *KSR*’s full impact will not be known for a number of years, the increase in the Federal Circuit’s invalidity decisions provides evidence that the Court is applying the new, flexible obviousness regime, but is unwilling to completely depart from its pre-*KSR* obviousness jurisprudence.

prior art teachings’ can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art.” 127 S.Ct 1727, 1775 (2007).

2. Andy Gibbs, “Comparison of Statistical Quality Indicators of Patents in CAFC Decisions Before and After ‘*KSR v. Teleflex*,’” 2006-2008, p. 7 (http://www.ipfrontline.com/downloads/Patent_Quality_KSR.pdf (accessed Sept. 15, 2008)) (The study addressed favorable decisions for the defendants in general but did not analyze obviousness in particular).

3. 499 F.3d 1293 (Fed. Cir. 2007) (“*Aventis II*”).

4. *Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, 2006 U.S. Dist. LEXIS 48246,48375-77 (E.D. Va 2006) (“*Aventis I*”).

5. *Aventis II*, 499 F.3d at 1301.

6. 504 F.3d 1249 (Fed. Cir. 2007).

7. Id. at 1262 (internal citations omitted).

8. Id. (internal citations omitted).

9. *In re Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002).

10. Id. at 1343 (quoting *McGinley v. Franklin Sports Inc.*, 262 F.3d 1339, 1351-52 (Fed. Cir. 2001)).

11. *KSR*, 127 S.Ct at 1743.

12. 501 F.3d 1263 (Fed. Cir. 2007) (“*Forest Labs II*”).

13. *Forest Labs. Inc. v. Ivax Pharms. Inc.*, 438 F. Supp. 2d 479, 492 (D. De 2006) (“*Forest Labs I*”).

14. *Pfizer Inc. v. Apotex Inc.*, 480 F.3d 1348, 1360-69 (Fed. Cir. 2007).

15. *Pfizer Inc. v. Apotex Inc.*, 488 F.3d 1377 (Fed. Cir. 2007).



1. Under which a patent claim is only proved obvious if ‘some motivation or suggestion to combine the