

SWIMMING THROUGH A TSUNAMI

It's no exaggeration to say that patent law has been experiencing a series of earthquakes, the powerful tremors composed of a series of far-reaching Supreme Court and Federal Circuit decisions. Many basic assumptions have changed that guide the day-to-day practice of law: how to prepare patent applications, how to structure a technology license, how to prepare for patent litigation and avoid a finding of reckless infringement. Here are thoughts from practitioners on a legal landscape changed by three decisions: *MedImmune* and its implications for licensing, *KSR* and the shifted terrain of "obviousness," and *Seagate*, which redefines "recklessness" in patent infringement.

PATENTING THE "EUREKA" MOMENT

Breakthrough moments in the lab must be marshaled into the centerpiece of the patentee's story.

By Thomas Lihan and Robert Rhoad

The U.S. Supreme Court's decision in *KSR v. Teleflex* changed the landscape for the law of obviousness, and patent litigators must adapt their tactics to fit that new terrain. In this article, we will discuss several of the more important considerations that savvy practitioners should take into account in the post-*KSR* world.

Defining the "Person of Skill in the Art"

One of the most significant changes that *KSR* wrought was to widen the technical grasp of the hypothetical "person of ordinary skill in the art" (POSITA), the construct that will help the judge or jury decide if a patent should be invalidated for obviousness. The Court conferred on the POSITA permission to cobble together disparate references from other fields to arrive at the claimed invention, motivated by any variety of design demands, commercial trends, and market forces. This heightens the need to exercise care in defining the level of skill possessed by the POSITA.

For example, because the POSITA can combine references only to the extent permitted by his or her technical grasp, patentees may well want to limit that technical grasp by more narrowly defining the POSITA's level of expertise, so as to circumscribe the POSITA's technical agility, creativity, and thought processes. We saw this play out in the U.S. Court of Appeals for the Federal Circuit's recent decision in *Daiichi Sankyo v. Apotex*. There, the court's determination that the POSITA was an ear specialist, such as an otologist (as urged

by defendant Apotex), rather than a pediatrician or other general practitioner (as found by the district court), was a critical factor in the Federal Circuit's determination that the patent at issue, which was directed to a topical antibiotic compound to treat ear infections, was obvious.

The danger in "dumbing down" the POSITA, of course, is that while it may help deflect an accused infringer's obviousness assault, it may make the patent more vulnerable to a validity challenge on section 112 grounds, such as for lack of enablement. In particular, the lower the POSITA's skill level, the more express the patent's disclosure must be in order to enable the POSITA to practice the full scope of the claimed invention.

Although defining the POSITA has always been an issue, *KSR* heightens its significance. Indeed, in *Daiichi*, the Federal Circuit noted that the parties had provided "little more than conclusory arguments concerning this issue in their briefs" before the district court. Practitioners should avoid that mistake by giving the issue the attention it deserves—both in their presuit evaluations and in crafting their litigation tactics. Patentees will need, for instance, to exercise care in selecting patents and claims to assert which are supported by more express detail in the specification, rather than relying on the POSITA's background knowledge to fill in the gaps. This will allow litigators more flexibility in defining the POSITA in ways that minimize the POSITA's skill in combining references in a way that leads to obviousness under *KSR*.

Market Factors

KSR also heightens the importance of the state of the marketplace at the time the patent application was filed. The KSR opinion repeatedly highlights design demands, marketplace incentives, and commercial trends as a reason to assemble disparate teachings to achieve the claimed invention. This, in turn, highlights the value and importance of patents that are filed during periods of basic research, before the launch of products embodying claimed inventions, and of emphasizing features that represent a true technological advance, rather than a response to market-driven pressures. Teleflex lost, in large measure, because the Court found that the “state of the industry” at issue was sufficiently mature that it “would lead inevitably” to combinations of the claimed elements in its brake pedal.

This affects a variety of tactical considerations in any infringement litigation. In particular, patentees should begin the considerable task of collecting documentation and other evidence necessary to defend against obviousness attacks early on—before suit if possible. Given KSR’s emphasis on market pressures as providing motivation to combine various disparate teachings, patentees should try to mine their documents (including, e.g., laboratory notebooks, project reports, and marketing data) and personnel for evidence demonstrating, to the extent possible, that market incentives pointed in a myriad of directions, only one of which may have been the development of a product embodying the claimed invention. Litigators should identify the appropriate individuals with knowledge of the firm’s business objectives and market planning for potential selection to serve as the company witnesses, and have them prepared to be thoroughly knowledgeable of the full breadth of the patentee’s development efforts, including areas that did not bear fruit.

Likelihood of Success

In a similar vein, in performing any due diligence and/or litigation preparation, patentees should also be on guard against their own internal demonstrations of confidence in being able to achieve the claimed invention. Under KSR, obviousness may be made manifest by predictable results arising from the combination of known and familiar elements. Statements in project or marketing reports forecasting project success, or expecting the exact results

ultimately achieved will provide fodder from which an accused infringer can build its obviousness case. The existence and sources of any such predictive statements should be identified early on, and the full story behind the patentee’s confidence needs to be fleshed out to give the necessary context to combat the patent challenger’s reliance on sound bites depicting the patentee’s pronouncements of foreordained success. For example, the inventor’s “eureka” moments in the lab or elsewhere, or evidence of experimentation of slight variations yielding conflicting or drastically differing results, should be identified and marshaled as potential centerpieces of the patentee’s story of its invention.

Optimistic forecasts of hard-won success can provide fodder from which an infringer will build its obviousness case.

In a hypothetical case, imagine that, in the course of discovery, a memo from the patentee’s eager and enthusiastic marketing personnel is found, predicting the successful culmination of ongoing work to develop an embodiment of the invention, as if success were a foregone conclusion. The patent’s challenger will no doubt frame the document as a smoking gun in its obviousness case. What’s a patentee to do? The patentee must counter by developing evidence to show the difficulty in the experimentation, unforeseen variables creating unexpected barriers to success, and/or a reasonable level of uncertainty in achieving the invention, notwithstanding marketing pronouncements to the contrary. Reports and memorandums of a technical nature are especially critical here. While a corporate cheerleader’s overconfident marketing memo may still have some impact on the obviousness inquiry, abundant technical documentation prepared by skilled research personnel that places the eventual outcome of the development work as something much less than a scientific certainty can and should carry more weight, thereby blunting the effect of the damaging correspondence.

These are some of the more direct effects KSR may have, but many other tactical changes will likely be needed due to the sea change prompted by the decision. A well-counseled and prudent litigation strategy, taking due account of these changes, will help the patentee better navigate these uncharted and obstacle-filled waters. ■

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