“Obviously” a challenge: Patent survival statistics & tips

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Patents are a key to product life cycle management. Successfully using patents to extend a product line often boils down to the legal question of obviously. This is because an attempt to patent a modified technology is likely to be faced with the question of whether the newly proposed claims are “obvious” in light of the prior technology. What it takes to make a modification “nonobvious” over the prior art is one of the most important legal questions facing pioneering companies. It is the key to product life cycle management. And it is not an easy question.

Obviousness has become a higher hurdle in recent years. In jury trials, it was previously uncommon for judges to take up the question of obviousness directly; obviousness was viewed as a “fact question” that typically was resolved by the jury. When judges did take up the question, as in bench trials, obviousness was governed by a more demanding “teaching-suggestion-motivation” test; that is, new patent claims would not be found obvious unless the prior art contained statements that would have taught, suggested, or motivated a scientist to undertake the subsequent advance. This legal standard was rejected by the US Supreme Court in the 2007 case of KSR v. Teleflex. KSR held that factors such as market forces, design incentives, predictability of combining known elements, and prior teachings could be used to show that the claimed invention was simply the application of common sense and ordinary skill to solve a problem. Most importantly, KSR empowered judges to make the obviousness decision themselves, without having to submit the question to the jury. KSR applies to all technologies, and the result has been both that patents are harder to obtain and that more patents are found invalid.

Two years of case law have unfolded since KSR, and trends are beginning to emerge showing how various classes of patents are faring. Fish & Richardson PC has reviewed all reported opinions citing KSR through August 2009. The following statistics should give some hope to the biotechnology and pharmaceutical industries, in that their patents are surviving obviousness challenges more so than patents in other fields. This data highlights statistics from pharmaceutical patents, for which there are enough cases to make out the emerging trends. These results should be illuminating for the biotechnology field as well, given the uncertainties and complexities in the underlying technology.

Although the data set is still limited, the trends appear to indicate that patents to a new active pharmaceutical ingredient (“API”) are still king, having the best track record of surviving an obviousness challenge. Formulation patents (i.e., ones involving a new formulation of a known chemical entity) have historically had less success than new chemical entities, but are nonetheless surviving obviousness challenges more frequently than nonpharmaceutical patents. And the data appears to indicate that patentees will prevail on obviousness more frequently before juries than in bench trials. Following is the breakdown on these criteria.

At the US Court of Appeals for the Federal Circuit, pharmaceutical patents are holding up better than other patents. Of eleven pharmaceutical appeals from district courts since KSR that hinge on obviousness, eight were resolved favorably to the patentee. By contrast, when all appeals from district courts are accounted for, irrespective of technology, of the 36 obviousness appeals thus far, only 14 were resolved favorably to the patentee on obviousness (Figure 1).

Among pharmaceutical patents, API patents are holding up better than formulation patents. Because data is more limited for this set, we looked at all opinions, from both the trial court and appellate levels. Of thirteen API cases, ten were resolved favorably to the patentee, and of 22 formulation cases, fourteen were resolved favorably to the patentee (Figure 2). This is still a more than 50% success rate, but the data confirms that API patents are still the strongest patents in the courts.

Figure 1. Pharmaceutical patents withstand obviousness challenges better than do patents for other technologies before the Federal Circuit Court of Appeals.
At the trial court level, juries are more accommodating to patentees than are judges. Across all technologies, in those reported jury cases where obviousness was at issue, out of a total of 37 reported opinions, juries were favorable to the patentee in 30 cases. In bench trials, of 23 cases, 15 were resolved in favor of the patentee (Figure 3). Thus, if there is a procedural route to a jury, it recommended that it be taken.

The cases in which the patentees prevail tend to hinge on a few key factors for surviving an obviousness challenge. Unpredictability, surprise, and upsetting conventional wisdom are golden. As the Federal Circuit noted in upholding a patent of Ortho-McNeil Pharmaceutical against a generic challenge by Mylan, “[T]he inventor’s insights, willingness to confront and overcome obstacles, and yes, even serendipity, cannot be discounted.” Ortho-McNeil’s success in the courts came from its discovery that an intermediate in the synthesis of a diabetes drug could be used to treat epilepsy. The Federal Circuit emphasized Ortho-McNeil’s unexpected results and skepticism by others as to the effectiveness of the anti-epileptic in upholding the patent.

The Federal Circuit’s most recent ruling to date highlights the challenges that patentees may face. In Bayer v. Barr, the Federal Circuit struck down Bayer’s patent to a contraceptive formulation containing drospirenone, a diuretic known to reduce bloating. Due to drospirenone’s low solubility, it was known that micronization of the drug into tiny particles would increase its solubility and thus its bioavailability. However, due to drospirenone’s expected instability in the low pH environment of the stomach, it was thought that the particles would need an enteric coating to allow passage through the stomach into the intestine before release of the drug. In a control experiment, Bayer’s scientists discovered unexpectedly that despite micronization, uncoated drospirenone particles sufficiently survived the acid environment of the stomach. However, Bayer’s patent to this approach of using an uncoated micronized drug did not hold up. The Federal Circuit viewed the problem faced by the scientists as binary—either to use or not use an enteric coating on the micronized particles. In framing the discovery as a relatively straightforward choice “between two known options” instead of mapping out all the permutations of choices faced by the scientists, the court found that Bayer’s story collapsed to a “finite number of identified, predictable solutions,” and invalidated the patent. One judge dissented.

Bayer’s story is probably a familiar one to many companies—a limited number of “viable options” (a phrase seized on by the court) and a discovery with some unexpected results. Framing these facts in a winning story is the challenge.

One step that companies can undertake before litigation is to properly document the “surprise” of an invention. In view of the time lag that inevitably occurs between the “Aha!” moment in the laboratory and the inventor’s day in court, it is important that the inventor’s appreciation of the discovery be captured in contemporaneous documents. Without documents to point to that memorialize the discovery, an inventor’s testimony in court may sound unconvincing. Thus, laboratory notebooks and project reports should be managed with an eye toward telling a story at trial, and capturing the surprise, unexpected results, and debunking of conventional wisdom that can be key to obtaining lasting patent protection.

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