

FEBRUARY 23, 2005

VIEWPOINT

By **Bruce D. Sunstein**

Patents: Billions Riding on a Word

A fight between Merck and Teva Pharmaceuticals hinges on what "about" means, highlighting the difficulties in interpreting such documents

At the end of January, Merck & Co. lost a patent fight with Teva Pharmaceuticals. The battle was over a patent (No. 5,994,329) that Merck had obtained for a once-per-week form of Fosamax, its blockbuster treatment for osteoporosis. On appeal, the dispute boiled down to the meaning of a single word, "about."

That may seem silly, but the word appeared in an important place: The claims of the patent. So why's that important? The claims tell the world what the patent covers.

There are some rules to know about patent claims. No. 1: Every word counts. If a new product matches a patent in any way, then the product infringes on the protection. But there's a catch: If the claim covers anything preexisting, it's invalid.

AROUND AND ABOUT. One of the claims in dispute in the patent battle between Merck and Teva covered a method of treating osteoporosis by giving the patient an oral dose once a week of "about 70 mg" of a drug. Teva pointed to an earlier scientific publication suggesting the benefit of administering 80 mg of the drug weekly. That amounts to "about 70 mg," the company argued, and so the claim covers something old and is therefore invalid.

Merck pointed to language in the patent itself defining an entire phrase that included "about 70 mg" and some other words used in the claim as

an "amount...based on 70 mg of [the drug]." In Merck's view, a careful reading of its patent required "about 70 mg" to be understood as something close to "exactly 70 mg."

The trial court agreed with Merck and said that the patent claim was not invalid. Over a vigorous dissent, the Federal Circuit Court of Appeals reversed the decision. It said the patent was not clear enough for "about" to mean "exactly," so the word had its ordinary meaning of "approximately." The Federal Circuit's interpretation meant the claim was invalid -- and this could cost Merck many billions of dollars of Fosamax sales because the ruling could let generic drugs enter the market many years sooner than would otherwise be possible.

SETTING TERMS. The Federal Circuit, which hears virtually all patent appeals, has been worrying quite a bit lately about how to interpret patent claims. The full court is reconsidering a case (Phillips v. AWH Corp.) involving an interpretation of the word "baffle" in a patent claim. The court has received briefs addressing this question: Should claim interpretation be guided primarily by use of words in the patent or by meanings found in dictionaries? This isn't only a theoretical question -- as the Merck case shows, the answer can have big real-world consequences.

In the Phillips case, friend of the court briefs have been filed by patent bar associations urging the court to look first to the patent itself, rather than dictionaries, in attempting to understand what its claims mean. It's true that fights can often be avoided if lawyers draft definitions of terms right into the patent. And court decisions have said that "a patentee may be his own lexicographer." In other words, a patent can supply its own definitions. But in this case, the Federal Circuit ruled that Merck's patent wasn't clear enough in defining "about" for the patent's own definition to hold sway.

BLACK AND WHITE? In his dissent in the Merck case, Judge Randall Rader disagreed. He included a section entitled "Elect the Lexicographer Option at Your Own Risk," in which he pointed out that under prior decisions of the Federal Circuit, "an applicant, acting as a lexicographer, may define 'black' as 'white.'"

Judge Rader also noted the high rate of reversal by his Federal Circuit Court of trial court decisions involving claim interpretation. He complained about failure on the part of his court to pay sufficient heed to the language of the patent and to the decision of the trial court.

Beyond all this semantic wrangling, one thing is clear: We haven't heard the last word on the meaning of words in patent claims.

Bruce D. Sunstein is a patent lawyer and chairs the patent practice group at Bromberg & Sunstein LLP, Boston. His firm represented the Boston Patent Law Assn. in filing a friend of the court brief in the Phillips case