FEDERAL CIRCUIT PATENT LAW CASE UPDATE

Pfizer, Inc. v. Teva Pharms. USA, Inc., 05-1331 (Fed. Cir. Nov. 22, 2005) (Prost, J.)

The court affirmed the grant of a preliminary injunction against Teva and Ranbaxy based on Pfizer's assertion of a patent related to inhibitors used to treat hypertension. The court affirmed the claim construction that "saccharides" includes polysaccharides. This led to a likely case for infringement because Ranbaxy had admitted that under this construction it likely literally infringed.

Pfizer is the corporate parent of Warner-Lambert, the owner of U.S. Pat. No. 4,743,450. Pfizer and Warner-Lambert asserted the patent against Teva and Ranbaxy because Teva distributed Ranbaxy's generic version of Accupril®.

> The '450 patent relates to pharmaceutical compositions containing angiotensin converting enzyme ("ACE") inhibitors such as quinapril and their methods of manufacture. Quinapril and other ACE inhibitors can be used to treat hypertension, commonly known as high blood pressure. According to the '450 patent, however, many ACE inhibitors including quinapril are susceptible to degradation due to cyclization, hydrolysis, and oxidation. Cyclization occurs when one part of an ACE inhibitor compound reacts with a different part of the same compound to form a degraded, inactive "cyclized" compound. Hydrolysis and oxidation involve reactions with water and oxygen, respectively. Hydrolysis results in a degraded compound, and oxidation causes discoloration.
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> The '450 patent discloses minimizing cyclization, hydrolysis, and discoloration by using formulations containing a metal-containing stabilizer and a saccharide.

Teva originally filed an ANDA to sell a generic version of Accupril®, but later Ranbaxy approached Teva and the two entered into a distribution and supply agreement. Ranbaxy had filed its own ANDA, but Warner-Lambert did not respond to Ranbaxy's paragraph IV certification letter, nor file suit thereafter. Thus, the 30 month stay was not triggered.

In evaluating Warner-Lambert's potential for success on the merits, the court evaluated the claim construction.

> Ranbaxy contests the district court's construction of "saccharide" and "saccharides" as those terms are used in independent claims 1 and 16. According to Ranbaxy, the district court should have construed "saccharides" to mean "sugars." In Ranbaxy's view "sugars" would include polysaccharides with up to ten monosaccharide units but would not include polysaccharides, such as microcrystalline cellulose, with more than ten monosaccharide units.
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> The claim language itself does not support Ranbaxy's proposed construction. . . . It is important to note that the claims do not include the terms "sugar" or "sugars." Neither do the claims distinguish between polysaccharides having ten or less monosaccharide units and polysaccharides having more than ten monosaccharide units.

Moreover, the specification listed sugar and a sugar derivative as preferred. Listing the derivative argued against Ranbaxy's narrow construction. The court therefore concluded "that the district court did not err in construing 'saccharides' to include polysaccharides."

The court next determined that the infringement analysis supported granting the preliminary injunction.

> The district court did not clearly err in determining that Warner-Lambert is likely to prevail in its charge that Ranbaxy literally infringes claim 16. Ranbaxy conceded in the preliminary injunction hearing that its formulation "absolutely" literally infringes claim 16 if "saccharides" is construed to include polysaccharides. Given that concession and the fact that we have construed "saccharides" to include polysaccharides, we cannot help but conclude that the district court was on solid ground in finding that it is likely that Ranbaxy literally infringes claim 16.

The outcome was similar for the other claim at issue, claim 1, although the evaluation was based on expert testimony, not on Ranbaxy's admission.

The court also affirmed the determination that infringement under the DOE was likely, putting aside Ranbaxy's arguments that the dedication doctrine and all limitations (vitiation) rule would preclude the DOE.

Presuming harm, and finding that Ranbaxy did not rebut that presumption, despite Warner-Lambert's decision not to trigger the 30 month stay, the court evaluated the other preliminary injunction factors in Warner-Lambert's favor.

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