

Review and Analysis of Pfizer, Inc. v. Ranbaxy Laboratories Limited, F.3d 1284; 2006 U.S. App. LEXIS 19416; 79 USPQ2d 1583 (Fed. Cir. August 2, 2006)

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In Pfizer, Inc. v. Ranbaxy Laboratories Limited, F.3d 1284; 2006 U.S. App. LEXIS 19416; 79 USPQ2d 1583 (Fed. Cir. August 2, 2006), the CAFC held patent claim 6 invalid under the fourth paragraph of 35 USC 112 for failing to further limit the claim from which it depends.

Claim 1 reads as follows: "1. [R-(R*,R*)]-2-(4-fluorophenyl)-[beta],[delta]-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)-carbonyl]-1H-pyrrole-1-heptanoic acid n4 or (2R-trans)-5-(4-fluorophenyl)-2-(1-methylethyl)-N,4-diphenyl-1-[2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl]-1H-pyrrole-3-carboxamide; n5 or pharmaceutically acceptable salts thereof."

Claim 2 reads as follows: "2. A compound of claim 1 which is [R-(R*R*)]-2-(4-fluorophenyl)-β-d-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid."

Claim 6 reads as follows: "6. The hemicalcium salt of the compound of claim 2."

The important points are that claim 2 is limited to an acid compound, and that claim 6 attempts to define the salt of the acid compound of claim 2 by referring to claim 2. The Court found claim 6 invalid because it interpreted claim 6's reference to claim 2 to require claim 6 to include all limitations of claim 2, and therefore to define an acid. However, claim 6's recitation "hemicalcium salt" does not define (and in fact is inconsistent with) an acid.

An excerpt of the opinion showing the Court's legal reasoning follows:

We recognize that the patentee was attempting to claim what might otherwise have been patentable subject matter.[note 7 omitted] Indeed, claim 6 could have been properly drafted either as dependent from claim 1 or as an independent claim - - i.e., "the hemicalcium salt of atorvastatin acid." But, we "should not rewrite claims to preserve validity." Nazomi Commc'ns, Inc. v. Arm Holdings, PLC, 403 F.3d 1364, 1368 (Fed. Cir. 2005); see also Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed. Cir. 1999) ("[I]f the only claim construction that is consistent with the claim's language and the written description renders the claim invalid, then . . . the claim is simply invalid."). Ranbaxy correctly argues that claim 6 fails to "specify a further limitation of the subject matter" of the claim to which it refers because it is completely outside the scope of claim 2. We must therefore reverse the district court with respect to this issue and hold claim 6 invalid for failure to comply with § 112, ¶ 4.

The opinion also notes in footnote 3 that both parties stipulated that claim 6 was in fact a dependent claim. However, the stipulation was not a factor in the court relied upon it in its legal reasoning.

What this means in practical terms (unless this holding is overruled, and barring unusual facts) is that any claim in the form: "A first 'thing' of the second 'thing' of claim X" has a good chance of being invalid if the first 'thing' is not a species of the second 'thing.' In particular, claims like "2. A salt of the acid of claim 1" are likely invalid. The 'may' caveat exists for two reasons. As the opinion states, the parties stipulated that claim 6 was a dependent claim. Otherwise, it might have been construed as an incorporation claim. I find this possibility unlikely in view of the Court's reasoning. Second, a specification theoretically could expressly define "acid" to also include within its meaning "salt" since a patentee can be his own lexicographer. I doubt many issued patents having this type of claim contain such a definition.

Clearly, a large number of issued patent claims are likely invalid in view of this decision. An obvious course of action for all patentees in view of this decision is to review their portfolio of patents, licenses, and due diligence files, to see which U.S. patents and applications have claims of this nature, and then determine suitable follow up actions. Such actions would include canceling licenses, reissuing patents, presenting new claims in continuation applications, and proceeding with commercial activity otherwise precluded.

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