Keywords: **dependent claims; Section 112; invalidity; claim construction; generic drugs**

General: **Dependent claims must reference a previous claim and must further limit the subject matter of that claim. Failure to comply with this requirement invalidates the claim under 35 U.S.C. §112.**

Pfizer Inc. v. Ranbaxy Laboratories Limited
79 U.S.P.Q.2d 1583 (Fed. Cir. 2006)
Decided August 2, 2006

I. Facts

Defendant Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy") filed an Abbreviated New Drug Application ("ANDA") for a generic version of the cholesterol drug Lipitor®. Plaintiff-patentee Pfizer Ireland Pharmaceuticals and various Warner-Lambert entities ("Pfizer") filed four complaints alleging that the product in Ranbaxy's ANDA infringed U.S. Patent No. 4,681,893 ("the '893 patent") and 5,273,995 ("the 995 patent"). After a bench trial, the district court concluded that both patents were infringed and not invalid or unenforceable. Ranbaxy appealed the findings of infringement under both patents and also appealed the ruling that claim 6 of the '995 patent was not invalid for failure to comply with 35 U.S.C. §112, ¶ 4.

II. Issues

A. Was the district court's construction of claim 1 of the '893 patent to cover trans isomers of the claimed compound (atorvastatin calcium) incorrect?

B. Was claim 6 of the '995 patent invalid for failure to comply with §112, ¶ 4?

III. Discussion

A. No. The Federal Circuit upheld the district court's claim construction.

The specification of the '893 patent depicts four structural isomers (R-trans, S-trans, R-cis, S-cis) of atorvastatin calcium, the compound recited in claim 1. The specification expressly disclaimed the cis isomers, and the court did find any further disavowal of claim scope that would limit the claims to a mixture of the two trans isomers (trans-racemates). The court rejected Ranbaxy's arguments that "(1) one skilled in the art would represent a racemate by depicting one of its constituent enantiomers; (2) the specification only discloses reaction sequences that produce racemates; (3) during prosecution of foreign counterparts to the '893 patent, the patentee represented that its references to "trans" should be read as "trans-(±);" and (4) during prosecution of the '995 patent, the patentee argued that the '893 patent was limited to mixtures of enantiomers rather than the R-isomer." Regarding the first argument, the court held that even if depiction of an R-enantiomer commonly represents a racemate, it does not always represent only a racemate. The court found that restricting claim 1 on the basis that the reaction sequences described in the specification only produce racemates would improperly import limitations from the specification into the claims. Finally, the court ruled that the statements made during prosecution of foreign counterparts to the '893 patent and during prosecution of the "unrelated" '995 patent were irrelevant to claim construction.

B. Yes. Reversing the district court, the Federal Circuit found that dependent claim 6 failed to meet the requirements of 35 U.S.C. §112, ¶ 4 and was therefore invalid.

35. U.S.C. §112, ¶ 4 recites:

> Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Claim 1 of the '995 patent claims the following compounds: (1) atorvastatin acid; *or* (2) atorvastatin lactone; *or* (3) pharmaceutically acceptable salts thereof.

Claim 2, dependent on claim 1, recites *only* the atorvastatin acid.

Claim 6, dependent on claim 2, recites "[t]he hemicalcium salt of the compound of claim 2."

The Federal Circuit recognized that the patentee was trying to claim patentable subject matter, and that claim 6 could be proper as either an independent claim or as dependent on claim 1. However, the Federal Circuit agreed with Ranbaxy that claim 6 fails to "specify a further limitation of the subject matter" because the subject matter of claim 6 is completely outside the scope of claim 2. The court noted that claim 2 "does not include the pharmaceutically acceptable salts of atorvastatin acid," and the two claims deal with "non-overlapping subject matter."

The district court acknowledged that there might be a "technical problem" with the drafting of claim 6 but did not invalidate the claim, as it could not find any Federal Circuit precedent invalidating a patent due to §112, ¶ 4 deficiencies. Because of the lack of Federal Circuit precedent, and the fact that the PTO responds to §112, ¶ 4 deficiencies with an objection and not a rejection, the District Court concluded §112, ¶ 4 "to be limited to matters of form, rather than matters of substance." The Federal Circuit rejected these conclusions, citing previous case law that suggested a patent may be invalid because of §112, ¶ 4 violations and that failure to comply with *any* requirement of §112 is "expressly included' as an available defense to infringement under 35 U.S.C. §282. Further, the Federal Circuit did not see this as exalting form over substance, but rather a part of the overall statutory requirements for obtaining a patent, which may include procedural or technical aspects.