United States Court of Appeals for the Federal Circuit

04-1539, -1576

JANSSEN PHARMACEUTICA, N.V. and
JANSSEN PHARMACEUTICA PRODUCTS, L.P.,

Plaintiffs- Appellants

v.

EON LABS MANUFACTURING, INC.

Defendant-Cross Appellant.

DECIDED: June 13, 2005

Before SCHALL, Circuit Judge, ARCHER, Senior Circuit Judge, and PLAGER, Senior Circuit Judge.

ARCHER, Senior Circuit Judge.

Janssen Pharmaceutica, N.V. and Janssen Pharmaceutica Products, L.P. (collectively "Janssen") appeal the judgment of the United States District Court for the Eastern District of New York that Eon Labs Manufacturing, Inc.'s ("Eon") Abbreviated New Drug Application ("ANDA") does not infringe U.S. Patent 5,633,015 ("the '015 patent"). Eon cross-appeals the district court's judgment that the '015 patent is not invalid under 35 U.S.C. § 102(b) as a public use or the subject of an offer for sale. We affirm the district court's judgment.

I

The '015 patent, owned by Janssen, is directed to "beads" which are individual sugar cores coated with an antifungal drug and then seal-coated with a polymer layer. These beads are the building blocks of Janssen's itraconazole antifungal drug SPORANOX®.[1] Eon filed an ANDA seeking approval to make and sell a generic version of the SPORANOX® capsule. After receiving notice of Eon's ANDA, Janssen brought suit, asserting that Eon's ANDA infringed the '015 patent.

Claim 1 of the '015 patent, the only independent claim, reads as follows:

> 1. A bead comprising:
> a) a central, rounded or spherical core;
> b) a coating film of a hydrophilic polymer and an antifungal agent selected from the group consisting of itraconazole and saperconazole, and
> c) a seal-coating polymer layer, characterized in that the core has a diameter of from about 600 to about 700 µm (25-30 mesh).

'015 patent, col. 6, ll. 17-24. Following a bench trial, the district court held that

> one of ordinary skill in the art would understand that the patent teaches a composition of one or more beads containing a core with a diameter between 600 and 700 microns at the time the core is classified for use. . . . Thus, a diameter of 600 to 700 microns refers to the diameter as measured at the time the cores are separated by sieves, classified, and made available for sale to the drug manufacturer. . . . I clarify my construction as to how the size diameter claimed is determined, to mean the diameter as determined at the time of manufacture, that is, the time at which people practicing the patent would obtain the sugar spheres, and the time at which the particles are classified and labeled.

Janssen Pharmaceutica N.V. v. Eon Labs Mfg., Inc., 01-CV-2322 (NG) (MDG), slip op. at 15 (Jul. 28, 2004) ("Opinion and Order"). The court additionally found that Eon's ANDA did not infringe the '015 patent, either literally or under the doctrine of

[1] Each SPORANOX® gelatin capsule contains several hundred of these beads.

equivalents. Id. at 16, 20. Finally, in addressing Eon's counterclaims, the court ruled that the '015 patent was not invalid based upon public use or an offer for sale. Id. at 25.

Janssen appeals the district court's claim construction as well as its findings on infringement. Eon cross appeals the court's validity determinations. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II

A

Claim construction is an issue of law that we review de novo. Liquid Dynamics Corp. v. Vaughan Co., Inc., 355 F.3d 1361, 1367 (Fed. Cir. 2004). Infringement, whether literal or under the doctrine of equivalents, on the other hand, is a question of fact, and is reviewed for clear error. Golen Blount, Inc. v. Robert H. Peterson Co., 365 F.3d 1054, 1058 (Fed. Cir. 2004). Additionally, whether a patent is invalid for a public use or sale is a question of law based on underlying facts. Intel Corp. v. Int'l Trade Comm'n, 946 F.2d 821, 829 (Fed. Cir. 1991).

B

In determining the meaning of disputed claim language, we look first to the intrinsic evidence of record, examining the claim language itself, the specification, and the prosecution history. Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001) (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

Here, the issue is how to construe the claim terms "about 600 to 700 µm (25-30 mesh)." Janssen encourages us to all but ignore the parenthetical statement "25-30 mesh," arguing that the claim reads on a bead measuring between about 600-700 µm

across the center and the presence of the parenthetical should not change that interpretation. Janssen further asserts that measuring the diameter in terms of mesh cut looks beyond the plain meaning of the term "diameter." Eon, whose ANDA calls for cores measuring 20-25 mesh, naturally seeks a claim construction in which the mesh size is a positive limitation in the claim, or at least a product by process limitation. We believe that a claim construction in which "25-30 mesh" is a positive limitation best describes the invention of the '015 patent.

The shortcoming of Janssen's arguments is that they fail to take into account the patentees' description of what they invented. Specifically, whenever the written description describes the size of the cores, it always includes the mesh cut, see abstract line 2; col. 1, ll. 52, 53; col. 2, ll. 6, 12, 27; col. 3, line 23; col. 4, line 57; col. 5, line 18, and only rarely (twice) includes the micron size limitation (600-700 µm). Indeed, there are six places in the written description where the size of the cores is referred to only as "25-30 mesh" and nowhere is the micron size limitation referred to alone. Also counseling against adopting Janssen's proposed claim construction is the fact that we generally interpret claims so that no term is superfluous. See Merck & Co. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so."); Power Mosfet Techs., L.L.C. v. Siemens AG, 378 F.3d 1396, 1410 (Fed. Cir. 2004) (stating that interpretations of claims rendering claim terms superfluous is generally disfavored). Were we to conclude that claim 1 simply covers all cores having a diameter 600-700 µm across the center we would be rendering the phrase "25-30

mesh" superfluous. The mere fact that a limitation is placed within parentheses does not mean it is no longer a part of the claim.

Additionally, evidence adduced at trial suggests that a person of ordinary skill in the art reading the claims in conjunction with the written description would understand claim 1 to require cores selected according to the industry standard sieving process and not simply particles having a certain micron diameter. In the pharmaceutical industry, cores are measured and labeled based on the size sieve they fall through. For example, a group of particles that falls through a 25 mesh sieve but stays on top of a 30 mesh sieve will be labeled "25-30 mesh," with the particles generally having diameters in the range of 600-710 µm. Similarly, a group of particles that falls through a 20 mesh sieve but stays on top of a 25 mesh sieve will be labeled "20-25 mesh," with the particles generally having diameters in the range of 710-850 µm.[2] There is no dispute that drug manufacturers identify core size based on mesh cut for pharmaceutical use. In fact, even one of Janssen's research scientists testified that "mesh" "was an expression of the size of the sugar spheres, based, for example, on the number of sieve openings per surface unit." Thus, one having ordinary skill in this art would interpret "a diameter of from about 600 to 700 µm (25-30 mesh)" to describe cores 1) labeled 25-30

[2] At the time of manufacture and packaging for pharmaceutical use, 100% of the cores in a labeled product have fallen through the sieve with the larger openings and remained on top of the sieve with the smaller openings noted on the label. No manufacturer measures the size of individual cores. For quality control, a manufacturer performs analytical sieving (a second round of sieving) on a sample of the cores it intends to use to verify the sieves have produced a product which conforms to allowable specifications. To be within the standards of the American Society for Testing and Materials ("ASTM"), the distribution of particles in a given lot may contain up to 10% cores larger than the largest named sieve and up to 10% cores smaller than the smallest named sieve.

mesh at the time of manufacture and classification, and 2) having a particular diameter, about 600-700 µm.[3]

C

"Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device, i.e., when the properly construed claim reads on the accused device exactly." Amhill Enters., Ltd. v. Wawa, 81 F.3d 1554, 1564 (Fed. Cir. 1997). It is undisputed that Eon's ANDA product will be made using cores from a 20-25 mesh cut. Thus, none of Eon's ANDA cores would have been labeled 25-30 mesh at the time of manufacture and classification. Accordingly, Eon's ANDA cannot literally infringe claim 1 of the '015 patent.[4]

"Even if one or more of the claim limitations are not literally present in the accused device, thus precluding a finding of literal infringement, the claim may still be held infringed if equivalents of those limitations are present." Allen Eng'g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1345 (Fed. Cir. 2002) (citing Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 24 (1997)). Equivalents are assessed on a limitation-by-limitation basis. Warner-Jenkinson, 520 U.S. at 40.

The district court found "that the difference in core size [between that claimed in the '015 patent and Eon's ANDA cores] is not insubstantial and that the cores claimed in the '015 patent and Eon's ANDA cores are not equivalent. . . . " Order and Opinion at

[3] Janssen also asserts that the district court improperly construed the term "about." Because the meaning of this term has no effect on our infringement and validity analyses, we do not reach the issue of its correct interpretation.

[4] This is so regardless of the diameter of the cores used in Eon's ANDA. While most of these cores will have a diameter within the range of 710-850 µm, a small percentage could have a diameter within the claimed range of about 600-700 µm.

20.[5] This factual finding was based upon the court's determination that the testimony of Dr. Bodmeier, Janssen's expert, was unpersuasive. Specifically, the court was not moved by testimony that a core up to 100 microns smaller (30-35 mesh) is substantially different from a 25-30 mesh core, but a core up to 140 microns larger (20-25 mesh) is not. We can find no clear error in the court's rejection of this testimony. Additionally, Janssen has not directed us to any other evidence that suggests the court clearly erred in its determination.

Because Eon's ANDA does not meet the limitation "about 600-700 µm (25-30 mesh)" either literally or equivalently, we affirm the district court's findings of no infringement.

D

In its cross appeal, Eon asserts that the '015 patent is invalid under 35 U.S.C. § 102(b) as a public use or as the subject of an offer for sale. Specifically, Eon claims that a letter dated August 17, 1992, constituted an offer for sale more than one year before the critical date and that Janssen's clinical trials of its F12 SPORANOX® product in June-August 1991 was a public use more than one year prior to the critical date. The district court found the '015 patent not invalid based upon public use or because it was the subject of an offer for sale. We agree.

At the outset, we note Eon's assertion that the district court used an improper critical date in conducting its invalidity analysis. We cannot say that the court abused its

[5] In its doctrine of equivalents analysis, the district court made various statements about foreseeability, argument-based estoppel, and dedication to the public. While we do not agree with the court's analysis of these issues, we nonetheless affirm the finding of noninfringement on the basis of the court's insubstantial differences analysis.

discretion in not accepting Eon's eve-of-trial assertion that the critical date theretofore accepted by both parties was incorrect. However, given that we must make a validity determination concerning the '015 patent which could be considered law of the case in other disputes relevant to this patent, we believe that using the correct critical date, August 27, 1992, (the date asserted by Eon) is the prudent course of action. We also note that the district court did review the purported offer for sale even though it fell within what the court considered to be the one year statutory period.

The alleged offer for sale is a letter dated August 17, 1991, addressed to a senior pharmaceutical buyer at a wholesale company and announcing the launch of SPORANOX® antifungal capsules. As the district court noted, "Eon has not provided any evidence that shows whether or not the letter was ever sent to, or received by, any person, and no evidence of what the custom or the practice in the industry was in regard to a letter of this type." Order and Opinion at 25. Thus, even if the contents of the letter were sufficient to be an offer for sale such that the only thing any recipient had to do to form a binding contract was to "accept" the recommended order quantity, there is nothing in the record to suggest the "offer" was ever made. Accordingly, this letter does not demonstrate that the invention of the '015 patent was the subject of an offer for sale more than one year prior to the critical date.

The remaining issue is whether Janssen's clinical trials of the F12 SPORANOX® product constituted a public use under section 102(b). Public use includes "any use of [the claimed] invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor." Petrolite Corp. v. Baker Hughes Inc., 96 F.3d 1423, 1425 (Fed. Cir. 1996) (citing In re Smith, 714 F.2d 1127, 1134 (Fed. Cir.

1983)). We look to the totality of the circumstances when evaluating whether there has been a public use within the meaning of section 102(b). Sinskey v. Pharmacia Ophthalmics Inc., 982 F.2d 494, 498 (Fed. Cir. 1992). The circumstances may include: the nature of the activity that occurred in public; the public access to and knowledge of the public use; whether there was any confidentiality obligation imposed on persons who observed the use; whether persons other than the inventor performed the testing; the number of tests; the length of the test period in relation to tests of similar devices; and whether the inventor received payment for the testing. See Allied Colloids, Inc. v. Am. Cyanamid Co., 64 F.3d 1570, 1574 (Fed. Cir. 1995). There may be additional factors in a particular case relevant to the public nature of the use or any asserted experimental aspect. Netscape Communications Corp. v. Konrad, 295 F.3d 1315, 1320 (Fed. Cir. 2002).

Here Eon offers the following as evidence that the 1991 clinical trials were a public use: none of the subjects of the trials were bound by confidentiality restrictions; all of the subjects knew they were getting itraconazole; the participating physicians were only bound to protect the confidentiality of the patients and the protocol, not the composition of F12; the inventors were not involved in the clinical trials; no results were reported back to the inventors; and the trials did not deal with improving the F12 composition but rather were directed to determining the bioequivalency of taking F12 while fasting and after a normal meal.

In response, Janssen first emphasizes the confidentiality statement. This emphasis is misplaced, because the confidentiality statement merely obligated the doctors to protect the confidentiality of the patients and the protocol, and nowhere in the

protocol is mention made of the invention of the '015 patent. Indeed, nothing is said about the drug in the protocol other than the subjects will be taking two 100 mg itraconazole capsules for each dosage. Janssen correctly argues, however, that because the composition of F12 (including the beads and the size of the cores contained in the capsule) was never released to the doctors or the subjects of the trials, this fact weighs in favor of a finding that the use was not public.

In its additional arguments as to why the clinical trials were a non-public use, Janssen points to the fact that the trials were closely monitored by Janssen; there was a strict protocol that was to be followed. In other words, the participating physicians were not able to dispense itraconazole capsules to anyone they wished to in any amount the physician deemed appropriate. Moreover, any unused drug had to be returned to Janssen. Further, Janssen received no money for these trials, and there were only twenty-eight people involved in the study.

The district court found that the "evidence supports Janssen's position that the use was confidential and controlled by Janssen." Order and Opinion at 22. Based on the totality of the circumstances, Eon has not demonstrated on appeal that the district court erred in reaching its conclusion that Eon had failed to show by clear and convincing evidence that the 1991 clinical trials of the F12 SPORANOX® product was a public use. Accordingly, we affirm the district court on this issue.

III

For the reasons stated above, we affirm the district court's judgment of noninfringement and its dismissal of Eon's claims of invalidity.