United States Court of Appeals for the Federal Circuit

03-1634, -1635

TAP PHARMACEUTICAL PRODUCTS, INC.
(formerly known as Tap Holdings, Inc.),
and TAKEDA CHEMICAL INDUSTRIES, LTD.
(now known as Takeda Pharmaceutical Company, Ltd.),

Plaintiffs/Counterclaim Defendants-Cross Appellants,

and

WAKO PURE CHEMICAL INDUSTRIES LTD.,

Plaintiff-Appellee,

and

ABBOTT LABORATORIES,

Counterclaim Defendant,

v.

OWL PHARMACEUTICALS, L.L.C.
and OAKWOOD LABORATORIES, L.L.C.,

Defendants/Counterclaimants-Appellants.

William F. Cavanaugh, Jr., Patterson, Belknap, Webb & Tyler LLP, of New York, New York argued for plaintiffs/counterclaim defendants-cross appellants and plaintiff-appellee. With him on the brief was Stuart E. Pollack. Of counsel on the brief were Henry J. Renk and Bruce M. Wexler, Fitzpatrick, Cella, Harper & Scinto, of New York, New York.

Thomas H. Shunk, Baker & Hostetler LLP, of Cleveland, Ohio, argued for defendants/counterclaimants-appellants. With him on the brief was Kyle B. Fleming. Of counsel on the brief was Richard A. Sharpe, Pearne & Gordon, L.L.P., of Cleveland, Ohio.

Appealed from: United States District Court for the Northern District of Ohio

Judge Solomon Oliver, Jr.

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DECIDED: August 18, 2005

Before NEWMAN, BRYSON, and GAJARSA, Circuit Judges.

BRYSON, Circuit Judge.

TAP Pharmaceutical Products, Inc., Takeda Chemical Industries, Ltd., and Wako Pure Chemical Industries, Ltd., (collectively, "TAP") filed suit against OWL Pharmaceuticals, L.L.C., and Oakwood Laboratories, L.L.C., (collectively, "OWL") in the United States District Court for the Northern District of Ohio. TAP alleged that OWL had infringed 12 patents owned by TAP. The allegations were based on OWL's filing of an Abbreviated New Drug Application seeking approval from the Food and Drug Administration to market a generic version of the drug leuprolide. TAP markets leuprolide, a sustained-release formulation for treating prostate cancer, under the trade name Lupron Depot. OWL counterclaimed, seeking a declaration that the patents were not infringed, were invalid, and were unenforceable. On a motion for summary judgment, the district court held that OWL did not infringe the asserted claims of U.S. Patent Nos. 5,476,663 ("the '663 patent"), 5,631,020 ("the '020 patent"), and 5,631,021 ("the '021 patent"). In a separate summary judgment ruling, the court held that OWL infringed claim 1 of U.S. Patent No. 4,728,721 ("the '721 patent") and claims 1-4 of U.S. Patent No. 4,849,228 ("the '228 patent").

At trial, the jury found that the '721 and '228 patents were not invalid and that OWL's infringement was not willful. Following the trial, the district court addressed OWL's claim that the '721 patent and the '228 patent were unenforceable due to inequitable conduct. The court rejected that claim on the ground that OWL failed to show by clear and convincing evidence that TAP had engaged in inequitable conduct by failing to cite two prior art references to the Patent and Trademark Office ("PTO") during the prosecution of the patents.

The parties have not appealed the jury's verdict on either of the issues resolved by the jury. OWL, however, has appealed from the district court's summary judgment of infringement with regard to the '721 and '228 patents, and from its decision that the '721 and '228 patents are not unenforceable. TAP has cross-appealed from the court's summary judgment of noninfringement with regard to the '663 patent, the '020 patent, and the '021 patent. We affirm the district court's judgment in all respects.

I

OWL's appeal is limited to the '721 and '228 patents. The '721 patent is directed to certain biodegradable high molecular polymers that have good aging stability and are useful as excipients in pharmaceutical preparations. The '228 patent is directed to microcapsules for use in sustained-release drug formulations in which the biodegradable high molecular polymers disclosed in the '721 patent are used as excipients. The two patents describe the use of the polymers and microcapsules in connection with sustained-release treatments in which leuprolide is delivered to patients through injection. The use of the microcapsules allows the injected drug to be delivered to the patient's system at a constant rate over a long period of time.

In prior art microcapsules, the presence of water-soluble low molecular compounds in the excipient negatively affected the sustained-release drug delivery system by causing (1) "high initial burst," i.e., the initial release of too much drug from the microcapsule; (2) low drug incorporation during the process of creating the microcapsules; and (3) poor long-term stability of the polymers used in the microcapsules. The '721 and '228 patents address those problems by reducing the levels of water-soluble low molecular compounds to a very low concentration.

A

Claim 1 of the ’721 patent is representative of the claims at issue in both patents with regard to the limitation in dispute. That claim reads as follows:

> A biodegradable high molecular polymer useful as an excipient in producing a pharmaceutical preparation comprising a copolymer or homopolymer of about 50-100 mole percent of lactic acid and about 50-0 mole percent of glycolic acid having a weight average molecular weight of about 2,000 to 50,000 and wherein the content of water-soluble low molecular compounds, as calculated on the assumption that each of said compounds is a monobasic acid, is less than 0.01 mole per 100 grams of said high molecular polymer.

The language in dispute for purposes of OWL’s appeal on claim construction is “comprising a copolymer . . . of lactic acid and . . . of glycolic acid.” OWL argues that the reference to copolymers of lactic acid and glycolic acid requires that the copolymers be made from lactic acid and glycolic acid as starting materials. The district court, however, construed that language to include “copolymers composed of lactic acid and glycolic acid mers produced by any method, including the use of lactide and glycolide.”

Under OWL’s construction, the claimed copolymers would have to be made by direct polymerization from lactic acid or glycolic acid. Under the district court’s construction, the claims were not limited to copolymers made by direct polymerization. Instead, under the district court’s construction, the claimed polymers could be made by a different method such as the “ring-opening” method in which lactic acid and glycolic acid are first converted into cyclic dimers, known as lactide and glycolide. The rings of those dimers are then opened by a catalyst, after which they react to form copolymer chains consisting of repeating units of lactic acid and glycolic acid.

We uphold the district court’s claim construction, which was the product of a careful analysis of the claim language, the specifications of the two patents, the

prosecution history, and the extrinsic evidence provided to the court. As the district court observed, neither the language of the claims nor the specification of either patent explicitly sets forth the starting materials for making the copolymers, nor do the claims or the specification require that the copolymers be produced by direct polymerization. To the contrary, while the common specification of both patents lists examples of polymerization by using lactic acid and glycolic acid as the starting materials, the specification explicitly provides that the biodegradable high molecular polymer that serves as the starting material for performing the method of the invention "may be produced by any method." '721 patent, col. 1, ll. 63-65.

The district court based its claim construction in part on treatises that recognize that copolymers of lactic acid and glycolic acid can be made either by direct polymerization or by ring opening. Based on that evidence, the district court concluded that one of ordinary skill in the art would consider the terms "copolymer of lactic acid and glycolic acid" to be synonymous with the term "copolymer of lactide and glycolide." Indeed, OWL's expert, Dr. Colin Pitt, testified that at the time the patent application was filed, a person of ordinary skill in the art would use the terms "lactic acid" and "glycolic acid" interchangeably with the terms "lactide" and "glycolide" because "the language was relatively loose at that point in time" with respect to the use of those terms.

As to the prosecution history of the two patents, OWL argues that because the prosecution files contained statements regarding the preparation of the polymers by combining lactic acid and glycolic acid, the examiner intended to exclude the use of other compounds as the appropriate starting materials for the claimed high molecular

polymer. The prosecution history, however, does not exclude the use of other compounds, such as lactide or glycolide, to make the copolymer.

Finally, OWL argues that the prosecution history of the European application corresponding to the '721 patent excludes copolymers made from lactide and glycolide because TAP stated to the European examiner that the invention did not include a polymer made from lactide or glycolide. As the district court explained, however, while the applicant for the European patent characterized the claims in that manner, the European patent examiner rejected that characterization, stating that the applicant "does not appear to be correct in saying that the polymer of the present application is different from polymerized glycolide and/or lactide." In light of the European examiner's rejection, it is reasonable to conclude that TAP receded from that characterization of its claims, which it did not repeat in the course of the prosecution of its U.S. patents. It was therefore proper for the district court to attribute little weight to the statements made to the European examiner.

OWL does not dispute that under the district court's claim construction, it literally infringed TAP's patents. Because we sustain the district court's claim construction, we uphold the court's determination that OWL infringed the '721 and '228 patents.

B

OWL argues that the '721 patent and the '228 patent are unenforceable because of inequitable conduct, based on TAP's purported suppression of a published European application, EP 0 052 510 A2 ("the Kent application"). During the prosecution of the '721 patent, TAP received notice of the Kent application in a European search report, which was generated in connection with the prosecution of the European counterpart to

the ’721 patent. The European search report listed the Kent application as relevant as “technical background.” Shortly thereafter, TAP submitted the European search report to the examiner who was reviewing the application that became the ’721 patent. The search report was filed as a supplemental Information Disclosure Statement (“IDS”), which was submitted after the notice of allowance for the ’721 patent was issued. In addressing OWL’s argument that the late submission of the Kent application constituted inequitable conduct that rendered the ’721 and ’228 patents unenforceable, the district court found that the Kent application was not material to the patentability of the claims of those patents and that TAP did not intend to deceive the PTO by withholding the application until after issuance of the notice of allowance for the ’721 patent.

OWL argues that the Kent application was material and that TAP intended to deceive the PTO by failing to disclose it until the last minute. OWL further contends that TAP misrepresented the nature of the Kent application when TAP finally disclosed that reference in the supplemental IDS.

As to materiality, OWL argues that the Kent application discloses a copolymer of lactic acid and glycolic acid and teaches a method of purifying high molecular polymers. The purification method is not directly disclosed in the Kent application, but is disclosed in a reference cited in the Kent application, U.S. Patent No. 3,773,919 (“the Boswell patent”). The Boswell patent describes a method of purification that involves “pouring the [target] solution into a large volume of a nonsolvent . . . .” Boswell patent, col. 9, ll. 1-3. OWL also relies on the listing of the Kent application in the European search report to demonstrate the materiality of the application.

Information is considered material when there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1179 (Fed. Cir. 1995), citing In re Jerabek, 789 F.2d 886, 890 (Fed. Cir. 1986). If the withheld information is merely cumulative in light of other references considered by the examiner, the information is not material. Molins PLC, 48 F.3d at 1179, citing Scripps Clinic & Res. Found. v. Genentech, Inc., 927 F.2d 1565, 1582 (Fed. Cir. 1991). The district court applied the correct legal standard and, after a detailed analysis of the materiality issue, found the Kent application not to be material. The court based its materiality determination on the differences between the Kent application and the '721 patent and on its conclusion that the Kent application was cumulative of other prior art that was before the PTO during the prosecution of the '721 patent. With respect to the differences between the Kent application and the '721 patent, the court found that the Kent application and the Boswell patent cited therein "do not teach that water-soluble low molecular compounds are problematic and do not teach testing for such compounds. They also do not encourage treatment of polymers with water." Instead, the court concluded, Boswell discloses "treating polymers with organic solvents, which would primarily dissolve and remove compounds other than water-soluble low molecular compounds." With respect to whether the Kent application was cumulative to references already before the examiner, the court relied in particular on U.S. Patent No. 4,273,920 ("the Nevin patent"), entitled "Polymerization Process and Product," and an article by Colin Pitt, entitled "Sustained Delivery Systems" ("the Pitt article").

The district court found that the Kent application and the Nevin patent both disclose the same relevant polymers, except that the Nevin patent discloses the polymers in a manner that is even closer to the claims of the ’721 patent, because the Nevin patent contains additional descriptive material, such as molecular weight ranges and inherent viscosity limitations. The district court therefore found that TAP’s failure to disclose the Kent application was not material, given that the Nevin patent was submitted to the examiner during prosecution and was considered by the examiner. The examiner found that the only difference between the Nevin patent and the ’721 patent was the limitation requiring that the content of water-soluble low molecular compounds in the polymer be less than 0.01 mole per 100 grams of the polymer.

Likewise, the district court found that the Pitt article describes a method of treating polymers that is identical to the method of purification described in the Boswell patent cited in the Kent application. The court further found that the Pitt article discloses not only the relevant method of purification, but also a polymer of lactic acid. The court therefore concluded that the Boswell patent, and hence the Kent application, were cumulative in light of the Pitt article.

OWL argues that the Kent application is not cumulative because it covers both the relevant method of purification and the relevant polymer, while each of the other two references omits either the purification method or the polymer. Specifically, OWL contends that while the Pitt article teaches only the relevant method of purification, it fails to disclose the relevant polymer because it discloses a polymer of only one acid, i.e., a “homopolymer,” as opposed to a polymer consisting of both lactic acid and glycolic acid, i.e., a “copolymer” of both acids. OWL also contends that while the Nevin

patent teaches copolymers of lactic acid and glycolic acid, it does not disclose a method of purifying high molecular polymers.

OWL's argument relies in large part on the assumption that a homopolymer is not the same as a copolymer for purposes of determining whether the Kent application is cumulative. In light of the fact that the claim refers to a "copolymer or homopolymer," however, it was not unreasonable for the court to treat both types of polymers similarly. Therefore, we see no clear error in the district court's analysis, and we affirm the district court's finding that the Kent application is cumulative of the Pitt article.

Regarding the Nevin patent, we agree with OWL that the district court did not explicitly address whether the Nevin patent contains a purification method and that it focused instead on the issue of the patent's disclosure of the polymer. Nevertheless, OWL fails to demonstrate how the district court erred in its determination, particularly in view of the Nevin patent's disclosure of a method of purifying high molecular polymers by using organic solvents. Nevin patent, col. 3, ll. 47-68. In any event, to the extent that the district court erred in finding that the Kent application is cumulative of the Nevin patent, that error is harmless in light of the court's finding that the Kent application was cumulative of the Pitt article and therefore not material.

We also uphold, as not clearly erroneous, the district court's conclusion that there was not clear and convincing evidence that TAP intended to mislead the PTO by withholding the Kent application until it submitted its supplemental IDS. OWL argues that TAP intentionally postponed the disclosure of the Kent application until it was too late, as a practical matter, for the examiner to review it. OWL further argues that TAP made a false statement to the PTO at that time because its patent attorney stated with

respect to the Kent application that "[n]o technique is disclosed in this reference for purifying polymers." The attorney's statement is misleading, according to OWL, because the Kent application disclosed a technique for purifying polymers through its incorporation by reference of the Boswell patent, which taught such a technique.

The district court based its finding that TAP did not intend to deceive the PTO on several factors. First, the court noted that the European search report indicated that the European Patent Office did not believe the Kent application was material, because it characterized the Kent application as merely technological background and thus not material to patentability. Moreover, the court observed that TAP submitted the European search report to the examiner within a month after receiving it. Finally, the court concluded that TAP introduced "significant evidence demonstrating that the '721 applicants did not believe the [Kent application] to be material," including "credible evidence that [the inventor] did not believe that [the Kent application] incorporates Boswell to the extent it disclosed any purification techniques." Credibility findings are highly factual determinations that are almost invariably left to the trial court. Syntex LLC v. Apotex, Inc., 407 F.3d 1371, 1384 (Fed. Cir. 2005). We are not persuaded that the district court's credibility determination was insupportable or that there is any other reason to find that the court committed clear error in finding that TAP did not act with an intent to deceive the PTO. Accordingly, we affirm the district court's ruling that the '721 and '228 patents are not unenforceable for inequitable conduct.

II

TAP's cross-appeal involves the '663 patent, the '021 patent, and the '020 patent. Those three patents are directed to extending the period during which certain

microcapsules can be stored by interspersing molecules of sugars among the microcapsules. Claim 1 of the '663 patent is representative of the asserted claims. It provides:

> A prolonged release microcapsule for injection, which comprises particles containing a water-soluble drug, the particles being dispersed in a spherical microcapsule matrix composed of a copolymer of lactic acid and glycolic acid having a comonomer ratio within the range of about 100/0 to 50/50 and an average molecular weight within the range of about 5,000 to 200,000, the spherical microcapsule matrix having an average diameter of 2 to 200 μm and an excipient selected from the group consisting of mannitol, sorbitol, lactose and glucose, which particles are produced by in-water drying.

TAP disputes the district court's construction of the claim term "particles containing a water-soluble drug, the particles being dispersed in a spherical microcapsule matrix." Relying on language from the specification and testimony by OWL's expert, Dr. Pitt, the district court construed the term "particles" in that limitation to contain both a drug and a drug-retaining substance.

We agree with the district court's construction. While nothing in the claim specifically refers to a "drug-retaining substance," the specification makes clear that the phrase "particles containing a water-soluble drug" must be interpreted as requiring both a drug and some substance in which to retain the drug. As the district court noted, not only do all of the 31 examples in the specification describe the use of particles containing a drug and a drug-retaining substance, but the specification provides that a drug-retaining substance "must be used in sufficient amount to ensure that the initial viscosity of the inner aqueous layer in the water-in-oil emulsion described hereinafter will not be lower than about 5000 centipoises . . . ." '663 patent, col. 4, ll. 49-52 (emphasis added). The specification further describes the drug-retaining substance as

a benefit of the invention, stating that "[s]ince a drug retaining substance is employed, the water-soluble drug can be incorporated in the microcapsule more easily and efficiently than by the conventional drying in solvent technique." Id., col. 10, ll. 11-14. That description is supported by the comparative data found in Table 3 and the accompanying explanation, which show that the drug is more easily incorporated in the microcapsule due to the addition of a drug retaining substance such as gelatin. See id., col. 12, ll. 48-53 ("when the in water drying technique . . . is carried out without gelatin . . . , the takeup ratio are as low as 1.9 to 6.7% whereas the takeup ratio for the microcapsules according to this invention are as high as 44.0% to 71.5%"). Finally, in describing how the microcapsules are made, the specification provides that "[t]he prolonged release microcapsule of the present invention is made by preparing a water-in-oil emulsion comprising an inner aqueous layer containing said water-soluble drug and a drug retaining substance . . . ." Id., col. 1, ll. 33-34.

TAP contends that the claims do not require inclusion of a "drug-retaining substance," for two principal reasons. First, TAP argues that the district court's construction is too narrow because the claim employs the word "containing," which TAP asserts has a well-established meaning identical to "comprising." TAP argues that the meaning of "containing" is "having at least the named component" and therefore that "particles containing a water-soluble drug" means that the particles must be composed "either (1) wholly of water-soluble drug or (2) partially of water-soluble drug plus additional ingredients." The word "containing," however, has two possible meanings as applied to the claims at issue in this case: (1) the one TAP suggests, and (2) the one adopted by the district court, i.e., one substance encompassed within another. In light

of the two different possible meanings for the term "containing," it was entirely reasonable for the district court to look to the specification as well as extrinsic evidence to determine the manner in which the term was used in the three patents at issue. Intel Corp. v. VIA Techs., Inc., 319 F.3d 1357, 1367 (Fed. Cir. 2003).

TAP's second argument is that the district court improperly relied on the testimony of OWL's expert, Dr. Pitt, in finding that the claimed particles require a drug-retaining substance because the word "containing" is not a technical term and the court therefore should not have resorted to extrinsic evidence to determine the meaning of the term as used in the patents. TAP, however, relies too heavily on the characterization of the word "containing" as a non-technical term. As the district court correctly pointed out, a word describing patented technology takes its definition from the context in which it was used by the inventor. See Anderson v. Int'l Eng'g & Mfg., Inc., 160 F.3d 1345, 1348-49 (Fed. Cir. 1998). While the term "containing" is not a technical term, the term is essential in helping to describe the patented technology. As a result, the term cannot be defined by some ordinary meaning isolated from the proper context, and it was appropriate for the district court not only to consider the intrinsic evidence, but also to consider Dr. Pitt's interpretation of that evidence, both in context and from the perspective of a person of ordinary skill in the art. See Phillips v. AWH Corp., No. 03-1269, slip op. 18-19 (Fed. Cir. July 12, 2005) (en banc).

We therefore uphold the district court's interpretation of the phrase "particles containing a water-soluble drug" to require the presence of a drug-retaining substance along with the drug. TAP does not dispute that, under the district court's claim construction, summary judgment of no literal infringement is proper. Moreover, we

agree with the district court that a finding of infringement under the doctrine of equivalents would vitiate an essential limitation of the claim, i.e., the presence of the drug-retaining substance. Because OWL's product does not infringe the '663 patent, the '021 patent, or the '020 patent, either literally or under the doctrine of equivalents, this court affirms the district court's grant of summary judgment of noninfringement as to those patents.

Each party shall bear its own costs for this appeal.

AFFIRMED.