United States Court of Appeals for the Federal Circuit

06-1021, -1022, -1034

ABBOTT LABORATORIES
and CENTRAL GLASS COMPANY, LTD.,

Plaintiffs-Appellants,

v.

BAXTER PHARMACEUTICAL PRODUCTS, INC.
and BAXTER HEALTHCARE CORP.,

Defendants-Cross Appellants.

R. Mark McCareins, Winston & Strawn LLP, of Chicago, Illinois, argued for plaintiffs-appellants. With him on the brief were Edward L. Foote, Raymond C. Perkins, Peggy M. Balesteri, James F. Herbison, and Timothy M. Schaum.

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

Judge Ronald A. Guzman

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DECIDED: November 9, 2006

Before BRYSON, Circuit Judge, ARCHER, Senior Circuit Judge, and GAJARSA, Circuit Judge.

GAJARSA, Circuit Judge.

Plaintiffs Abbott Laboratories and Central Glass Company (collectively "Abbott") appeal from a judgment of noninfringement of U.S. Patent No. 5,990,176 ("the '176 patent") by the United States District Court for the Northern District of Illinois. Defendants Baxter Pharmaceutical Products, Inc. and Baxter Healthcare Corp. (collectively "Baxter") cross-appeal the district court's determination that the asserted claims are valid and its refusal to find unenforceability due to inequitable conduct. This is our second hearing of this case; following our first, we reversed the district court's claim construction and remanded for trial. Abbott Labs. v. Baxter Pharm. Prods., Inc.,

334 F.3d 1274 (Fed. Cir. 2003). The district court conducted a bench trial, then further construed the claims at issue and found them valid and enforceable but not infringed. Abbott Labs v. Baxter Pharm. Prods., Inc., No. 01-CV-1867 (N.D. Ill. Sept. 26, 2005). This appeal timely followed.

Because we hold the asserted claims of the '176 patent to be anticipated by the disclosure in U.S. Patent No. 5,684,211 ("the '211 patent"), we reverse the district court's validity judgment.

I. BACKGROUND

A. The technology

Sevoflurane is a fast-acting, highly effective inhalation anesthetic. However, pure sevoflurane has a serious problem, unknown at the time of its invention and original shipment: it degrades in the presence of Lewis acids. Lewis acids are essentially defined as any species with an empty electron orbit leading to electron affinity and are common enough that avoiding exposure of sevoflurane to Lewis acids is quite difficult. Among the products of the degradation reaction is hydrofluoric acid, which is highly dangerous if inhaled. '176 patent col.1 ll.52-57. The original containers in which Abbott shipped its product had Lewis acids exposed on their interiors. The hydrofluoric acid thus produced etched the containers' glass surfaces, exposing even more Lewis acids, resulting in a vicious-cycle cascading reaction that seriously compromised Abbott's product while on the shelf and forced a recall.

After investigating the cause of the degradation, Abbott discovered the source of the problem. It also found a solution: water mixed in with sevoflurane will bind to and deactivate Lewis acids, protecting the sevoflurane from the degradation reaction.

A deliberate addition of water to sevoflurane ran counter to the conventional wisdom at the time: previously, Abbott had sought to minimize its product's water content. Abbott filed a patent application on the degradation-preventing combination of water or other "Lewis acid inhibitors" with sevoflurane, which issued as the '176 patent at issue here.

B. Prior proceedings

Baxter sought to ship its own sevoflurane product. On January 26, 2001, it filed an amended Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") covering its own sevoflurane product. Baxter filed with the FDA a certification of noninfringement and invalidity of the '176 patent pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (commonly known as a "paragraph IV certification"), which created the cause of action giving rise to this suit under 35 U.S.C. § 271(e)(2).

There are multiple product and method claims at issue. Claim 1 of the '176 patent is representative:

> An anesthetic composition comprising: a quantity of sevoflurane; and a Lewis acid inhibitor in an amount effective to prevent degradation by a Lewis acid of said quantity of sevoflurane, said Lewis acid inhibitor selected from the group consisting of water, butylated hydroxytoluene, methylparaben, propylparaben, propofol, and thymol.

'176 patent col.11 ll.21-29. The other claims at issue speak to using water specifically, methods of combining sevoflurane and Lewis acid inhibitors to produce the above-mentioned composition, or both. Id. at cols.11-12.

This case came before us for the first time when we reviewed the district court's construction of the phrase "amount effective to prevent degradation" to require at least 131 parts per million ("ppm") of water and its consequent summary judgment of noninfringement. Abbott, 334 F.3d at 1277. We disagreed with that construction, noting that "an effective amount of any given Lewis acid inhibitor will vary according to the

conditions to which sevoflurane is subjected," making construction referencing particular ranges of water content inappropriate. Id. at 1278. We vacated the district court's summary judgment and remanded. Id. at 1283. On remand, the district court conducted a bench trial. It determined that the term "to prevent degradation" had been left unconstrued, Abbott, No. 01-CV-1867, slip op. at 7, and concluded that "sevoflurane is degraded if it contains degradants in amounts greater than 300 ppm." Id. at 16. It found Abbott's literal infringement evidence to be unpersuasive, id. at 27, and Abbott's doctrine of equivalents argument to be barred by prosecution history estoppel, id. at 31. It addressed Baxter's claim that the patent was unenforceable due to inequitable conduct, but declined to so hold. Id. at 48.

Baxter made two distinct invalidity arguments. It first argued that since some lots of the pre-recall sevoflurane sold by Abbott had not degraded, there had been a prior sale which would bar the patent. The district court found insufficient evidence that those lots had actually been exposed to Lewis acids, making a finding that they had contained water "in an amount effective to prevent degradation" unsupportable. Id. at 44. Baxter's second argument was that the '211 patent disclosed a composition of water-saturated sevoflurane that met all the limitations of the asserted claims. Id. at 37-39. The district court noted some of our holdings finding anticipation even where, as here, there was no knowledge at the time of the relevant properties of the prior art. Id. at 40-41 (citing Atlas Powder Co. v. IRECO, Inc., 190 F.3d 1342, 1348-49 (Fed. Cir. 1999); SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1343-44 (Fed. Cir. 2005); Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1378-80 (Fed. Cir. 2003)). However, it concluded that the '211 patent did not anticipate. Id. at 43. That decision was based on

its reading of our decision in Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., in which we noted that "[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." Id. at 42 (quoting 246 F.3d 1368, 1376 (Fed. Cir. 2001) (emphasis added by district court)). It concluded that since the '211 patent disclosed an "intermediate step" in the manufacture of sevoflurane, "the patent's purpose was not to produce sevoflurane in its final useable form," in distinction to the purpose of the '176 patent, which "involves a final step in production." Id. at 42. The district court reasoned that since the patents' purposes were different, the Bristol-Myers Squibb distinction foreclosed a finding of anticipation. Id. at 42-43.

All of these rulings by the district court are before us via either Abbott's appeal or Baxter's cross-appeal. Abbott challenges the claim construction, arguing that the intrinsic evidence of the '176 patent permits more than 4,000 ppm of impurities before the sevoflurane may be considered "degraded." Abbott also challenges the district court's findings on literal and doctrine of equivalents infringement. Baxter challenges enforceability and validity, the latter in light of both the '211 patent and the alleged prior sale. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

A. Standard of review

Patent claims are presumed to be valid, 35 U.S.C. § 282, and the party seeking to show invalidity must prove facts supporting invalidity by clear and convincing evidence. N. Am. Vaccine, Inc. v. Am. Cyanamid Co., 7 F.3d 1371, 1379 (Fed. Cir. 1993). Since this case comes to us from a trial without jury, we review the district

court's findings of fact for clear error and its legal conclusions de novo. Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1565 (Fed. Cir. 1987).

B. The '211 patent

The '211 patent was applied for in 1995 and awarded to Kawai et al. in November 1997. Appellant Central Glass Co. is the assignee. The parties do not dispute that the '211 patent predates the '176 patent for the purposes of 35 U.S.C. § 102, and the facts about what the '211 patent teaches are in relevant part undisputed. It discloses a technique for purifying sevoflurane for "use[] as a pharmaceutical and particularly as an inhalation anesthetic," '211 patent abstract, which involves the addition of water. If the steps of its Illustration 1, Table 2 are practiced, the result will be sevoflurane that is saturated with water, unable to absorb any more moisture. Saturation implies that the sevoflurane contains an amount of water sufficient to prevent it from degrading due to Lewis acids.

At the time, however, knowledge of the beneficial nature of a water-sevoflurane mix was wholly lacking in the art. The district court describes the matter succinctly:

> [P]rior to [the '176 patent] invention no one had any idea that Lewis acids had the potential to degrade sevoflurane. Further, no one was aware of the stabilizing effect water would have to prevent Lewis acid degradation. In fact, water was considered an impurity and was removed from sevoflurane to the extent possible during the manufacturing process that included the teachings of the '211 patent.

Abbott, No. 01-CV-1867, slip op. at 39. Thus, the '211 patent discloses a particular composition and claims a process for making that composition, but does not teach the advantageous feature of that composition whose discovery led to the patent in suit.

C. Unknown properties and anticipation

Our cases have consistently held that a reference may anticipate even when the relevant properties of the thing disclosed were not appreciated at the time. The classic case on this point is Titanium Metals Corp. v. Banner, 778 F.2d 775 (Fed. Cir. 1985). In Titanium Metals, the applicants sought patent protection on an alloy with previously unknown corrosion resistance and workability properties. Id. at 776. The prior art reference was an article by two Russian scientists that disclosed in a few data points on its graphs an alloy falling within the scope of the claims of the patent in suit. Id. at 776-77. There was no sign that the Russian authors or anyone else had understood the later-discovered features of the alloy thus described. Id. at 780-81. Despite the fact that "the applicants for patent had discovered or invented and disclosed knowledge which is not to be found in the reference," we held that the Russian article anticipated the asserted patent claims. Id. at 782. The Titanium Metals rule has been repeatedly confirmed and applied by this court. See, e.g., In re Crish, 393 F.3d 1253, 1258-59 (Fed. Cir. 2004) (citing cases; holding asserted claims covering a gene's nucleotide sequence anticipated where the gene, though not its particular sequence, was already known to the art); In re Cruciferous Sprout Litig., 301 F.3d 1343, 1349-50 (Fed. Cir. 2002) (inventor's recognition of substances that render broccoli and cauliflower particularly healthy does not permit patent on identifying broccoli seeds or preparing broccoli as a food product); Atlas Powder, 190 F.3d at 1347-1350 (holding asserted claims covering air mixed into an explosive composition anticipated by prior art that necessarily also contained air as claimed, even though benefits of the air were not recognized). Indeed, the rule did not originate with Titanium Metals. See Ansonia

Brass & Copper Co. v. Elec. Supply Co., 144 U.S. 11, 18 (1892) ("[T]he application of an old process or machine to a similar or analogous subject, with no change in the manner of application and no result substantially distinct in its nature, will not sustain a patent even if the new form of result had not before been contemplated."); In re Pearson, 494 F.2d 1399, 1403 (C.C.P.A. 1974) (inventor's recognition that prior-art compound inhibited defects in peanut plants did not suffice to grant patent protection on that compound); In re Benner, 174 F.2d 938, 942 (C.C.P.A. 1949) ("[N]o provision has been made in the patent statutes for granting a patent upon an old product based solely upon discovery of a new use for such product.").

The general principle that a newly-discovered property of the prior art cannot support a patent on that same art is not avoided if the patentee explicitly claims that property. "[A] prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." Schering, 339 F.3d at 1377 (citing Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991)). "[I]nherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure." Id. (citing Cruciferous Sprout, 301 F.3d at 1351).

Abbott's objection here is merely that at the time of the '211 patent, nobody knew that the water-saturated sevoflurane that patent disclosed had the property of resisting the Lewis acid degradation reaction. Just as in Titanium Metals, that lack of knowledge is wholly irrelevant to the question of whether the '176 patent claims something "new" over the disclosure of the '211 patent; the claimed property of resistance to degradation is found inherently in the disclosure. Since the '211 patent discloses sevoflurane

saturated with water – i.e., unable to absorb any additional water to further protect it from the degradation reaction – it anticipates the claims of the ’176 patent. This is true under any definition of the term “prevent degradation” that the claims might reasonably bear, so we need not construe that phrase with numerical exactitude in order to reach our decision.

The district court nonetheless found the patent valid due to the purpose-based distinction we drew in Bristol-Myers Squibb. Abbott, No. 01-CV-1867, slip op. at 42-43 (citing 246 F.3d at 1376). As a threshold matter, we note that that distinction is applicable only to process claims. Bristol-Myers Squibb states that “new uses of known processes may be patentable,” citing in support the definition of “process” found at 35 U.S.C. § 100(b). 246 F.3d at 1376. The case does not speak to composition claims; the district court therefore committed legal error by applying it to sustain the validity of those claims of the ’176 patent that cover a mixture of sevoflurane and water. As to the ’176 patent’s process claims, we agree that Bristol-Myers Squibb needs to be considered, but we disagree with the concept that the processes described in the ’176 patent are not “directed to the same purpose,” id., under the meaning of Bristol-Myers Squibb. Both the ’211 and the ’176 patents disclose methods which help to ensure that sevoflurane will be of high purity at the time it is administered to patients. The ’211 patent discloses a method of achieving that end by adding water and then distilling the solution, which results in removing impurities from the sevoflurane, while the ’176 patent accomplishes the same objective by merely adding water, which results in safeguarding the sevoflurane against impurities generated by the presence of Lewis acids. All of the steps of the ’176 patent are thus disclosed in the ’211 patent in furtherance of the same

purpose: the delivery of safe, effective sevoflurane anesthetic. All that is contributed by the method claims of the '176 patent is the recognition of a new property of the prior art process. We hold today, as we did in Bristol-Myers Squibb, that "the claimed process here is not directed to a new use; it is the same use." Id.; see also Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 809-10 (Fed. Cir. 2002) (explaining that an inventor may not obtain a patent on a process having the same steps as a prior art process, in which the new process merely identifies a new, advantageous property of the prior art process).

We also do not find it material that the district court found the anticipating method in the '211 patent to be "an intermediate step" in the manufacture of sevoflurane. Abbott, No. 01-CV-1867, slip op. at 42. The product of that method was an anesthetic sevoflurane composition with sufficient water to prevent Lewis acid degradation—exactly what is claimed by the '176 patent. Commercial finality is not claimed.

III. CONCLUSION

For the reasons given above, we reverse the district court's judgment that the asserted claims of the '176 patent are valid. Since all asserted claims are invalid, we do not reach questions of infringement or inequitable conduct.

REVERSED.

No costs.