

United States Court of Appeals for the Federal Circuit

04-1273, -1274

INVITROGEN CORPORATION,

Plaintiff-Appellant,

v.

BIOCREST MANUFACTURING, L.P.,
STRATAGENE HOLDING CORP., and STRATAGENE, INC.,

Defendants-Cross Appellants.

Francis M. Wikstrom, Parsons Behle & Latimer, of Salt Lake City, Utah, argued for plaintiff-appellant. With him on the brief were C. Kevin Speirs and Kristine Edde Johnson. Of counsel on the brief was Alan W. Hammond, Invitrogen Corporation, of Carlsbad, California.

Marc R. Labgold, Patton Boggs LLP, of McLean, Virginia, argued for defendants-cross appellants. With him on the brief were Scott A.M. Chambers and Kevin M. Bell; and Richard J. Oparil, of Washington, DC.

Appealed from: United States District Court for the Western District of Texas

Judge Sam Sparks

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Defendants-Cross Appellants.

DECIDED: October 5, 2005

Before RADER, DYK, and PROST, Circuit Judges.

RADER, Circuit Judge.

On remand from this court, the United States District Court for the Western District of Texas, on summary judgment, determined that Biocrest Manufacturing, L.P., Stratagene Holding Corporation, and Stratagene, Inc. (collectively Stratagene) infringed Invitrogen Corporation's (Invitrogen's) U.S. Patent No. 4,981,797 (issued Jan. 1, 1991) (the '797 patent), and that the '797 patent was not invalid for indefiniteness, although it was invalid because of public use under 35 U.S.C. § 102(b). Invitrogen Corp. v. Biocrest Mfg., No. A-01-CA-167-SS (W.D. Tex. Feb. 12, 2004) (Invitrogen II). Although not specifically enumerating all of the counterclaims on which judgment was obviated due to its holding on invalidity, the trial court rendered final judgment sufficient to give

this court jurisdiction under 28 U.S.C. § 1295(a)(1) (2000). See Pandrol v. Airboss, 320 F.3d 1354, 1362-63 (Fed. Cir. 2003) (“What essentially is required is some clear and unequivocal manifestation by the trial court of its belief that the decision made, so far as it is concerned, is the end of the case.”). This court affirms the trial court’s decisions on infringement and on non-invalidity due to indefiniteness. Because the district court relied on an incorrect understanding of public use, this court reverses the trial court’s judgment of invalidity on that ground and remands.

I.

The '797 patent involves the introduction of recombinant DNA molecules into receptive E. coli cells to improve the cells’ “competence,” *i.e.*, their ability to take up and establish exogenous DNA and replicate this DNA as they multiply. See '797 patent, col. 1, ll. 11-13. A cell that accepts alien DNA is called a transformable cell.

Claim 1 of the '797 patent claims:

A process for producing transformable E. coli cells of improved competence by a process comprising the following steps in order:

- (a) growing E. coli in a growth-conductive medium at a temperature of 18°C to 32°C;
- (b) rendering said E. coli cells competent; and
- (c) freezing the cells.

'797 patent, col. 10, ll. 27-32 (emphasis added). Stratagene makes thirty-four competent E. coli cell lines by a process “including the steps of incubating cells at 37°C, growing the cells in a fermenter at 26°C, and freezing the cells.”

Invitrogen sued Stratagene for infringement on March 12, 2001. The district court construed the claims and then granted Stratagene’s summary judgment motion of non-infringement. Invitrogen appealed to this court, disputing the lower court’s

construction of both “improved competence” in the preamble and “growing” in step (a). This court decided that the trial court had correctly construed the term “improved competence.” Invitrogen Corp. v. Biocrest Mfg., 327 F.3d 1364, 1370 (Fed. Cir. 2003) (Invitrogen I). This court noted that the term required only a general increase in competence, as compared with that generally obtained when cells are prepared by either (1) growing the cells at 37°C, rendering them competent, and freezing them, or (2) growing the cells at 37°C, rendering them competent, and not freezing them. Id. At the same time, however, this court decided that the trial court had incorrectly construed “growing.” Id. This court construed that term to permit preparatory steps in advance of step (a), including growth of E. coli at a temperature outside the range in step (a). Id. Thus, the trial court received the case on remand.

On remand, the trial court properly applied this court’s construction of “growing” by stating that “the temperature of the medium in which the E. coli cells are grown” before step (a) “does not matter.” The district court then found literal infringement of claims 1, 2, 4, 5, 7, 8, 11, 14, and 15 of the ’797 patent; decided that Claim 1 was not indefinite under 35 U.S.C. § 112, ¶ 2; and found the claims invalid under the public use provision of 35 U.S.C. § 102(b). The court dismissed all other motions as moot. See Invitrogen II.

II.

This court reviews a grant of summary judgment de novo, determining whether the evidence in the record raises any genuine dispute about material facts. In this review, all reasonable factual inferences are drawn in favor of the non-moving party. See In re Cruciferous Sprout Litig., 301 F.3d 1343, 1346 (Fed. Cir. 2002), cert. denied,

538 U.S. 907 (2003). Whether a patent is invalid due to public use under § 102(b) is a question of law based on underlying questions of fact. Netscape Communications Corp. v. Konrad, 295 F.3d 1315, 1321 (Fed. Cir. 2002). A patent is presumed valid. 35 U.S.C. § 282 (2000). Overcoming the presumption requires a showing of facts proved by clear and convincing evidence. Connell v. Sears Roebuck & Co., 722 F.2d 1542, 1549 (Fed. Cir. 1983). That standard of proof also applies in the summary judgment context. Nat'l Presto Indus., Inc. v. W. Bend Co., 76 F.3d 1185, 1189 (Fed. Cir. 1996). Overall, this court makes an independent determination, applying the standards for summary judgment. Group One, Ltd. v. Hallmark Cards, Inc., 254 F.3d 1041, 1045 (Fed. Cir. 2001).

The Federal Circuit applies its own law with respect to issues of substantive patent law and certain procedural issues pertaining to patent law, but applies the law of the regional circuits on non-patent issues. Institut Pasteur v. Cambridge Biotech Corp., 186 F.3d 1356, 1368 (Fed. Cir. 1999). Therefore, this court reviews the district court's evidentiary rulings under the law of the United States Court of Appeals for the Fifth Circuit for an abuse of discretion. Snap-Drape, Inc. v. Comm'r of Internal Revenue, 98 F.3d 194, 197 (5th Cir. 1996).

The parties do not dispute that Invitrogen used the claimed process before the critical date, in its own laboratories, to produce competent cells. Invitrogen did not sell the claimed process or any products made with it. The record also shows that Invitrogen kept its use of the claimed process confidential. The process was known only within the company. Stratagene does not dispute that the claimed process was maintained as a secret within Invitrogen until some time after the critical date.

35 U.S.C. § 102(b) states that a person shall be entitled to a patent unless “the invention was . . . in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.” 35 U.S.C. § 102(b) (2000) (emphasis added). In Pfaff v. Wells, the Supreme Court considered the meaning of the phrase “the invention” in § 102(b). Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 60 (1998). The Court explained that analysis under § 102(b) involves two separate inquiries, one evaluating whether “the invention” was complete and ready for patenting, and the other evaluating whether that invention was “on sale.” Id. at 66-67. In that context, the Court found no role for this court’s “totality of the circumstances” test, which directed a court to consider the circumstances surrounding the alleged offer for sale together with the circumstances surrounding the stage of development of the invention that may have been prematurely exploited in the market. See id. at 66, n.11. In place of that “totality of the circumstances” test, the Court formulated the now-familiar test that evaluates both whether the product was subject to a commercial offer for sale (i.e., was it “on sale”) and whether the invention was “ready for patenting” (i.e., was there an “invention” at the time of the sale). See id. at 67. Following the Court’s guidance in Pfaff, this court rejected the totality of the circumstances test in the context of statutory bar disputes. See EZ Dock v. Schafer Sys., Inc., 276 F.3d 1347, 1351 (Fed. Cir. 2002) (“[T]his court now ‘follows the Supreme Court’s two-part test without balancing various policies according to the totality of the circumstances.’”) (quoting Weatherchem Corp. v. J.L. Clark, Inc., 163 F.3d 1326, 1333 (Fed. Cir. 1998)).

In Pfaff, the Court specifically considered the “on sale” portion of the § 102(b) statutory bar language, but in so doing, the Court noted that both the “on sale” and

“public use” bars were based on the same policy considerations. Id. at 64. The Court noted that both the on sale and public use bars of § 102 stem from the same “reluctance to allow an inventor to remove existing knowledge from public use.” Id. In Pfaff, the Court applied the separate components of its test to facts raising the “on sale” issue. Nonetheless, the Court’s analysis of the statutory term “invention,” or the ready for patenting prong, applies to both of the other parts of section 102(b), “on sale” and “public use.” Thus, the Supreme Court’s “ready for patenting test” applies to the public use bar under § 102(b). A bar under § 102(b) arises where, before the critical date, the invention is in public use and ready for patenting. This court notes that in applying the Pfaff two-part test in the context of a public use bar, evidence of experimental use may negate either the “ready for patenting” or “public use” prong. See EZ Dock, 276 F.3d at 1352 (recognizing an overlap of the experimental use negation and the ready for patenting standard).

This court’s decisions in Netscape Communications Corp. v. Konrad, 295 F.3d 1315 (Fed. Cir. 2002), and Bernhardt, L.L.C. v. Collezione Europa USA, Inc., 386 F.3d 1371 (Fed. Cir. 2004), do not compel a different analysis. In Netscape, this court considered a possible public use and formulated its inquiry as a “look to the totality of the circumstances when evaluating whether there has been a public use within the meaning of section 102(b).” Netscape, 295 F.3d at 1320 (citing Sinskey v. Pharmacia Ophthalmics Inc., 982 F.2d 494, 498 (Fed. Cir. 1992), a pre-Pfaff opinion). Likewise, in Bernhardt, this court stated, “[i]n determining whether an invention was in public use, a court ‘must consider how the totality of the circumstances comports with the policies underlying the on sale and public use bars.’” Bernhardt, 386 F.3d at 1379 (quoting

Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 549 (Fed. Cir. 1990) (a pre-Pfaff opinion)). The language in Netscape and Bernhardt should not be construed to resurrect a totality of the circumstances test for determining whether an “invention was . . . in public use . . . more than one year prior to the date” of the patent application. 35 U.S.C. § 102(b) (2000). Such a reading of Netscape and Bernhardt would be inconsistent with Pfaff and this court’s cases abandoning such a balancing test. See Pfaff, 525 U.S. at 66 n.11; EZ Dock, 276 F.3d at 1351; Weatherchem, 163 F.3d at 1333. The proper test for the public use prong of the § 102(b) statutory bar is whether the purported use: (1) was accessible to the public; or (2) was commercially exploited. Commercial exploitation is a clear indication of public use, but it likely requires more than, for example, a secret offer for sale. Thus, the test for the public use prong includes the consideration of evidence relevant to experimentation, as well as, inter alia, the nature of the activity that occurred in public; public access to the use; confidentiality obligations imposed on members of the public who observed the use; and commercial exploitation, see Allied Colloids, Inc. v. Am. Cyanamid Co., 64 F.3d 1570, 1574 (Fed. Cir. 1995). That evidence is relevant to discern whether the use was a public use that could raise a bar to patentability, but it is distinct from evidence relevant to the ready for patenting component of Pfaff’s two-part test, another necessary requirement of a public use bar.

The district court reasoned that Stratagene had used the claimed process in its own laboratories, more than one year before the ’797 application was filed, to “further other projects” beyond development of the claimed process and to acquire a commercial advantage. Stratagene admits that it used the claimed process in its own

laboratories before the critical date to grow cells to be used in other projects within the company. The district court determined that use of the invention in Stratagene's general business of widespread research generated commercial benefits. The district court examined the totality of the circumstances and found that this use was "public." See Invitrogen II. Stratagene argues, however, that this secret internal use was not "public use" under the applicable test, because it neither sold nor offered for sale the claimed process or any product derived from the process, nor did it otherwise place into the public domain either the process or any product derived from it. Under the proper test for public use under § 102(b), these facts do not erect a bar.

The basic tenet of U.S. patent law is that an original inventor gains an exclusive right to the invention. U.S. Const. art. I, § 8, cl. 8. Thus, an inventor's own work cannot be used to invalidate patents protecting his own later inventive activities unless, inter alia, he places it on sale or uses it publicly more than a year before filing. 35 U.S.C. § 102(b); see also In re Katz, 687 F.2d 450, 454 (CCPA. 1982); In re Facius, 408 F.2d 1396, 1406 (CCPA 1969) ("[C]ertainly one's own invention, whatever the form of disclosure to the public, may not be prior art against oneself, absent a statutory bar."). Section 102(a) denies any applicant for a patent an exclusive right to any invention already "known or used by others in this country" (emphasis added). On the other hand, § 102(b) can apply to the inventor's own actions. Section 102(b) expressly requires a "public use" in this country for a statutory bar to arise based on use by the inventor himself. See Pennock v. Dialogue, 27 U.S. 1, 23 (1829) (an applicant must be the "first and true" inventor to obtain a patent, but "if he shall put [the invention] into public use, or sell it for public use before he applies for a patent . . . this should furnish

another bar to his claim"); Katz, 687 F.2d at 454 ("Disclosure to the public of one's own work constitutes a bar to the grant of a patent claiming the subject matter so disclosed (or subject matter obvious therefrom)."). Further, to qualify as "public," a use must occur without any "limitation or restriction, or injunction of secrecy." Egbert v. Lippmann, 104 U.S. 333, 336 (1881); In re Smith, 714 F.2d 1127, 1134 (Fed. Cir. 1983).

In some cases, this court has determined that a use before the critical period was not public even without an express agreement of confidentiality. See, e.g., Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261 (Fed. Cir. 1986) (inventor's private use and demonstrations to colleagues were not public). For instance, in TP Laboratories, Inc. v. Professional Publishers, Inc., 724 F.2d 965 (Fed. Cir. 1984), the inventor was a dentist who installed the inventive orthodontic appliance in several of his patients. Although the inventor had not obtained any express promise of confidentiality from his patients, this court did not consider the use "public" because the dentist-patient relationship itself was tantamount to an express vow of secrecy. Id. at 972. In reaching that result, this court opined in general that secret use may be public "within the meaning of the statute, if the inventor is making commercial use of the invention under circumstances which preserve its secrecy." Id.* This court noted specifically that, under the facts of TP Laboratories, it

* Kinzenbaw v. Deere & Co., 741 F.2d 383 (Fed. Cir. 1984) is more definite concerning this dicta in TP Laboratories. Kinzenbaw states that commercial use trumps secrecy. Id. at 390. ("A commercial use is a public use even if it is kept secret.") However, this statement was also dicta in Kinzenbaw, because the court did not find it necessary to resolve the question of whether the use of the invention was secret or not. Id. A careful reading nonetheless shows that Kinzenbaw is consistent with the basic principle that a confidential use is not public under § 102 (b) unless there is commercial exploitation. The use in Kinzenbaw was not confidential. In that case, the jury had good reason to find Deere's widespread commercial exploitation of the invention "public." The facts showed that:

could find no “commercial exploitation” of the invention during the critical period, identifying “commercial exploitation” with sale of the device or a charge for its use of the invention within the confidential confines of the company to generate commercial benefits. Id. at 972-73. Thus, TP Laboratories bolsters the general point that an agreement of confidentiality, or circumstances creating a similar expectation of secrecy, may negate a “public use” where there is not commercial exploitation.

The classical standard for assessing the public nature of a use was established in Egbert. In Egbert, the inventor of a corset spring gave two samples of the invention to a lady friend, who used them for more than two years before the inventor applied for a patent. Egbert, 104 U.S. at 335. The invention was sewn into a corset and therefore, by its nature, not visible to the public. Thus, the Court had to decide whether such an invention could nevertheless be “public.” Although he later married the lady friend, the inventor in Egbert received no commercial advantage. Nonetheless, on these facts, the Court established the principle that it was indeed “public” use to give or sell the

Deere’s sales branch, acting through local independent dealers, made the invention available to farmers (called “customers” in Deere’s internal memoranda) for commercial use. Deere instructed the dealers to keep the units moving: “If one customer is not going to be using it for a few days and another customer could, please move it.” In 1973, the farmers used the planters for 1,000 hours in five states, and in 1974, for 500 hours in 11 states. By the end of 1974, 40,000 acres had been planted with the machines. . . . [T]hree years after it began using the invention, Deere filed the application for its patent.

Id. at 389-90. No wonder this court sustained a finding that Deere’s wide-spread activities were “primarily for commercializing the apparatus” and therefore public. Id.

invention “to another, to be used by the donee or vendee, without limitation or restriction, or injunction of secrecy.” Id. at 336.

As the Supreme Court pointed out in Pfaff, supra, secrecy of use alone is not sufficient to show that existing knowledge has not been withdrawn from public use: commercial exploitation is also forbidden. Invitrogen’s invention was not given or sold “to another,” or used to create a product given or sold to another, and was maintained under a strict obligation of secrecy. Without more, these circumstances are insufficient to create a public use bar to patentability.

The Supreme Court decided Electric Storage Battery Co. v. Shimadzu, 307 U.S. 5 (1939), in accord with the basic principle of Egbert. In Electric Storage Battery, an accused infringer put the invention into “public” use. The accused infringer’s public use came about because he had independently come upon both the method and the apparatus of the patents, and “continuously employed the alleged infringing machine and process for the production of lead oxide powder used in the manufacture of plates for storage batteries which have been sold in quantity.” Id. Thus, that case was marked by an outright commercial use of the invention by someone other than the applicant, long before the applicant’s filing date. Those facts allowed the Court to invalidate the patents at issue, and to observe that “[t]he ordinary use of a machine or the practice of a process in a factory in the usual course of producing articles for commercial purposes is a public use.” Id. at 20. Invitrogen, on the other hand, did not sell its invention or any products made with it, and kept the invention entirely confidential within the company, distinguishing this case from Electric Storage Battery.

While there are instances in which a secret or confidential use of an invention will nonetheless give rise to the public use bar, this is not such a case. In Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co., 153 F.2d 516 (2d Cir. 1946), the patentee used a secret process to recondition worn metal parts for its customers before the critical date. The Second Circuit correctly held “that it is a condition upon an inventor’s right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or [a patent].” Id. at 520. In contrast, there is no evidence that Invitrogen received compensation for internally, and secretly, exploiting its cells. The fact that Invitrogen secretly used the cells internally to develop future products that were never sold, without more, is insufficient to create a public use bar to patentability.

III.

Stratagene argues that it does not infringe the ’797 patent because its cells do not have “improved competence” as required by the patent’s preamble, although it admits that it practices each and every element of Claim 1, and does so in the claimed order. To settle this question, the court ordered tests on each of Stratagene’s thirty-four cell strains, to determine whether they exhibited “improved competence.” The tests compared cells grown at 37°C, rendered competent, then frozen, with cells grown at 37°C, rendered competent, but not frozen, and with cells prepared using the claimed process. Invitrogen’s expert supervised these tests. The tests showed that twenty-eight strains made using the Stratagene process exhibited enhanced competence, five exhibited decreased competence, and one exhibited no change.

Stratagene argues that those tests, presented in the form of an affidavit from the Invitrogen expert, are inadmissible. Stratagene contends that the affidavit lacks credibility because the expert did not conduct the tests personally, and thus does not have sufficient “personal knowledge” of the results. To the contrary, the district court carefully considered the admissibility of this evidence, and concluded that the expert had obtained sufficient personal knowledge through review of the records of the tests. This court detects no abuse of discretion in the district court’s decision to admit that evidence.

Stratagene also argues that the tests raise a genuine issue of material fact about the improved competence of Stratagene’s samples, because some of the samples did not exhibit improved competence. Again, to the contrary, a great majority of Stratagene’s samples did exhibit improved competence. The claim requires that the quantity of E. coli cells that take up and establish exogenous DNA to be generally increased. The tests show that general increase. In addition, Stratagene’s own inventor had recorded in his notebooks that he found “improved competence” when the cells of several cell lines were grown within the claimed range. The record contains no evidence that contradicts the general increase in competence observed in the tests. Therefore, the trial court properly resolved this issue as well.

IV.

Stratagene also argues that the ’797 patent is invalid for indefiniteness, objecting to the phrase “improved competence.” A claim is definite if “one skilled in the art would understand the bounds of the claim when read in light of the specification.” Personalized Media Communications, LLC v. ITC, 161 F.3d 696, 705 (Fed. Cir. 1998). Claims are

indefinite “if reasonable efforts at claim construction prove futile,” that is, if a claim “is insolubly ambiguous, and no narrowing construction can properly be adopted.” Exxon Research & Eng’g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001). Even if it is a formidable task to understand a claim, and the result not unanimously accepted, as long as the boundaries of a claim may be understood it is “sufficiently clear to avoid invalidity [for] indefiniteness.” Id. at 1375. Because this court construed the phrase “improved competence” in Invitrogen I such that one skilled in the art would understand the bounds of the claim, this court detects no unacceptable indefiniteness in that language in this appeal. The claim is not “insolubly ambiguous,” i.e., not indefinite.

Stratagene further argues that it would have had to practice the claimed process in order to determine if it was infringing, even though “[t]he primary purpose of the definiteness requirement is to ensure that the claims are written in such a way . . . that interested members of the public . . . can determine whether or not they infringe.” Oakley, Inc. v. Sunglass Hut Int’l, 316 F.3d 1331, 1340 (Fed. Cir. 2003). Indeed, the lower court had to have separate side-by-side tests done to determine whether Stratagene infringed, and other testimony indicates that tests were necessary to determine infringement. However, Oakley goes on to explain that “a patentee need not define his invention with mathematical precision in order to comply with the definiteness requirement.” Id. at 1341. Stratagene is really talking about the difficulty of avoiding infringement, not indefiniteness of the claim. “The test for indefiniteness does not depend on a potential infringer’s ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention.” SmithKline Beecham Corp. v. Apotex Corp.,

403 F.3d 1331, 1341 (Fed. Cir. 2005). This court's and the district court's constructions of the claim showed that it contained no material ambiguities, and therefore was not invalid for indefiniteness. See All Dental Prodx, LLC v. Advantage Dental Prods., Inc., 309 F.3d 774, 780 (Fed. Cir. 2002).

V.

Finally, Stratagene asks this court to consider its affirmative defenses of enablement, anticipation, and obviousness, as alternate grounds for invalidity. Final judgment by the district court included an order that invalidated the '797 patent based on public use under § 102(b), and on no other ground. The district court declared moot the other invalidity claims and made no final judgment on them. Therefore, under 28 U.S.C. § 1295(a)(1) (final judgment rule), this court declines to assert jurisdiction to consider an appeal on these issues.

This court reverses the trial court's judgment of invalidity due to public use, affirms the trial court's partial summary judgment of infringement and denial of Stratagene's motion for summary judgment of invalidity due to indefiniteness, and remands the case for further proceedings.

COSTS

Each party shall bear its own costs.

AFFIRM-IN-PART, REVERSE-IN-PART, and REMAND