United States Court of Appeals for the Federal Circuit

04-1570

ENZO BIOCHEM, INC.,

Plaintiff-Appellant,

v.

GEN-PROBE INCORPORATED,

Defendant-Appellee,

and

BECTON DICKINSON AND COMPANY,

Defendant-Appellee.

Charles A. Weiss, Kenyon & Kenyon, of New York, New York, argued for plaintiff-appellant. With him on the brief were Richard L. DeLucia, John R. Kenny and Patrice P. Jean. Of counsel were Anita Pamintuan Fusco and Henry N. Wixon.

William F. Lee, Wilmer Cutler Pickering Hale and Dorr LLP, of Boston, Massachusetts, argued for defendants-appellees. With him on the brief for Gen-Probe Incorporated were William G. McElwain and Nina S. Tallon. Of counsel was Henry N. Wixon. On the brief for Becton Dickinson and Company were Donald R. Ware, Barbara A. Fiacco, and Katherine J. Fick, Foley Hoag LLP, of Boston, Massachusetts. Of counsel were Denise W. DeFranco and Lauren T. Knapp.

Appealed from: United States District Court for the Southern District of New York

Judge Alvin K. Hellerstein

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DECIDED: September 30, 2005

Before LOURIE, LINN, and PROST, Circuit Judges.

LOURIE, Circuit Judge.

Enzo Biochem, Inc. ("Enzo") appeals from the summary judgment of the United States District Court for the Southern District of New York holding that United States Patent 4,900,659 is invalid under the on-sale bar of 35 U.S.C. § 102(b). Enzo Biochem, Inc. v. Gen-Probe, Inc., No. 99 Civ. 3548 (S.D.N.Y. July 27, 2004) ("Order"). Because the invention claimed in the '659 patent was the subject of an offer for sale before the critical date, we conclude that the patent is invalid and we affirm the district court's judgment.

BACKGROUND

Enzo is the assignee of the '659 patent, which relates to nucleic acid probes that selectively hybridize with the bacteria that cause gonorrhea, namely, Neisseria gonorrhoeae, as well as methods for using those probes to detect the bacteria. N. gonorrhoeae has a high degree of homology with Neisseria meningitidis, making it difficult to differentiate between the two bacteria. Enzo recognized the need for a chromosomal DNA probe specific for N. gonorrhoeae, and it derived three such sequences that preferentially hybridized with six common strains of N. gonorrhoeae over six common strains of N. meningitidis. '659 Patent, col. 3, l. 49 to col. 4, l. 14; col. 4, ll. 45-50. Enzo deposited those sequences in the form of a recombinant DNA molecule within an E. coli bacterial host at the American Type Culture Collection ("ATCC"). Id., col. 13, ll. 27-31.

Claim 1 of the '659 patent reads, in pertinent part, as follows:

> 1. A composition of matter that is specific for Neisseria gonorrhoeae comprising at least one nucleotide sequence for which the ratio of the amount of said sequence which hybridizes to chromosomal DNA of Neisseria gonorrhoeae to the amount of said sequence which hybridizes to chromosomal DNA of Neisseria meningitidis is greater than about five, said ratio being obtained by a method comprising the folllowing steps;

Id., col. 27, ll. 29-36. The method steps that follow are directed to obtaining the claimed ratio. Id., col. 27, l. 37 to col. 28, l. 26. Claim 4 of the patent is directed to the deposited probes, referenced by their accession numbers, and variations thereof:

4. The composition of claim 1 wherein said nucleotide sequences are selected from the group consisting of:

    a. the Neisseria gonorroheae [sic] DNA insert of ATCC 53409, ATCC 53410 and ATCC 53411, and discrete nucleotide subsequences thereof,
    b. mutated discrete nucleotide sequences of any of the foregoing inserts that are within said hybridization ratio and subsequences thereof; and
    c. mixtures thereof.

Id., col. 28, ll. 31-39. Claim 5, upon which Claim 6 depends, is directed to a method of conducting a hybridization assay with the deposited probes and variations thereof:

5. In a nucleic acid hybridization assay for the detection of Neisseria gonorrhoeae utilizing a polynucleotide probe, wherein said probe is contacted with a sample and the amount of any hybridized probe is detected, the improvement which comprises utilizing as said nucleotide probe a composition of claim 1, wherein said composition is labeled with a detectable marker.

Id., col. 28, ll. 40-46.

In June 1982, Enzo and Ortho Diagnostic Systems ("Ortho"), an affiliate of Cambridge Research Labs, entered into an agreement involving joint funding of research and development on "any human diagnostic product resulting from the program of research" (defined elsewhere in the agreement) "whether or not invented or developed by Enzo prior to the effective date of this agreement." In August 1983, the parties executed an amendment that made it clear that a probe for gonorrhea was part of the agreement. Importantly, paragraph 2.14 of the Enzo-Ortho agreement provided the following:

> ENZO shall supply to ORTHO and ORTHO shall purchase from ENZO for use in Licensed Products no less than ninety percent (90%) of ORTHO's United States requirements or seventy-five percent (75%) of ORTHO's worldwide requirements of Active Ingredients; provided, however, that ENZO shall have this right to supply and ORTHO shall have this obligation to purchase only with regard to Active Ingredients supplied to ORTHO at

> prices and time schedules which are reasonably competitive with those of other sources. . . .

The agreement also contained a paragraph 2.12 reading as follows:

> ENZO shall supply ORTHO at ENZO's fully allocated cost with all quantities of any Licensed Product reasonably required by ORTHO or any Affiliate for its own research, development, and test marketing, including that required to perform all preclinical and clinical studies.

In December 1984, apparently in satisfaction of paragraph 2.12, a key research and development provision of the agreement, Enzo transferred to Ortho a probe that was essentially the same as GC155, one of the three probes that Enzo deposited at the ATCC. Enzo filed a patent application on that subject matter in January 1986, more than one year after the transfer of the probe and the execution of the agreement, that eventually issued as the '659 patent in February 1990. The ATCC accession numbers were cited in the patent.

Enzo sued the defendants, Gen-Probe, Incorporated and Becton Dickinson and Company (collectively, "Gen-Probe"), for infringement of the '659 patent, and Gen-Probe moved for summary judgment that the claims were invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112. The district court granted Gen-Probe's motion, and Enzo appealed to this court. In 2002, we reversed the district court's grant of summary judgment and remanded the case to the district court because genuine issues of material fact existed regarding the satisfaction of the written description requirement. Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956 (Fed. Cir. 2002).

On remand, Gen-Probe moved for summary judgment of invalidity on different grounds, this time contending that all the claims of the '659 patent were barred by the

offer to sell contained in Enzo's agreement with Ortho, in violation of the 35 U.S.C. § 102(b) on-sale bar. In a detailed oral hearing conducted on July 27, 2004, the district court delivered its decision invalidating the '659 patent for violation of the on-sale bar. The court first considered whether the material offered for sale was within the scope of all of the claims. Because Enzo's success in its suit depended in part on its establishing that GC155 satisfies all the limitations of the claims for purposes of the enablement and written description requirements, the court determined that it was appropriate for Gen-Probe to rely on that contention as if proved for the purpose of Gen-Probe's own motion for summary judgment on the on-sale bar.

Second, the court determined that Enzo offered an embodiment of the '659 patent for sale prior to the critical date. The court found that the material transferred from Enzo to Ortho in December 1984 was GC155, the same material that was deposited at the ATCC in January 1986 as an embodiment of the invention. The court did not agree with Enzo that a genuine issue of material fact existed as to whether the probe sent to Ortho in December 1984 was identical to that deposited at the ATCC. Enzo had argued that the probe was still being developed and had only 700 base pairs, not the 840 base pairs that comprised ATCC 53411. The district court, on the other hand, relied on evidence in the form of laboratory notebooks and testimony from Enzo scientists that did not distinguish between various lengths of GC155.

Finally, the court evaluated Enzo's assertion of experimental use. The court found that Enzo had asserted that the probe that it delivered to Ortho was its final product, which it deposited at the ATCC, and thus that it had reduced the invention to practice. The court reasoned that the policy behind the rule that experimental use

negates an on-sale bar is to give the inventor the opportunity to reduce an invention to practice, and thus that what occurs after a reduction to practice cannot be experimental use; consequently, it concluded that Enzo's use was not experimental.

Enzo filed a Notice of Appeal on August 20, 2004. Gen-Probe then moved to dismiss the appeal, arguing that its counterclaim of unenforceability for inequitable conduct remained unadjudicated and that the district court's judgment was thus nonfinal. We determined that Gen-Probe's pending counterclaim rendered the district court's judgment nonfinal for purposes of appeal, but restated the principle that "a premature notice of appeal ripens upon subsequent action of the district court." Enzo Biochem, Inc. v. Gen-Probe, Inc., No. 99 Civ. 3548, slip op. at 7 (Fed. Cir. July 13, 2005) (quoting Pause Tech. LLC v. TiVo Inc., 401 F.3d 1290, 1295 (Fed. Cir. 2005)). Hence, we permitted the parties to seek remedial action in the district court and move to reinstate the appeal from a final judgment.

The parties returned to the district court requesting dismissal of Gen-Probe's pending counterclaim. The court agreed to dismiss the counterclaim, and Enzo filed an unopposed motion to reinstate the appeal. We granted that motion and now turn to the merits of the case, as the judgment of the district court is final and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review a district court's grant of summary judgment without deference, reapplying the same standard used by the district court. Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 149 F.3d 1309, 1315 (Fed. Cir. 1998). Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on

file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c).

A patent is presumed to be valid, see 35 U.S.C. § 282 (1994), and this presumption only can be overcome by clear and convincing evidence to the contrary. See, e.g., WMS Gaming Inc. v. International Game Tech., 184 F.3d 1339, 1355 (Fed. Cir. 1999). Whether an invention is "on sale" within the meaning of 35 U.S.C. § 102(b) is a question of law that we review de novo. Monon Corp. v. Stoughton Trailers, Inc., 239 F.3d 1253, 1257 (Fed. Cir. 2001). We review the district court's grant of summary judgment of invalidity by considering whether Gen-Probe established that there were no material facts in dispute and presented clear and convincing evidence, viewed in a light most favorable to Enzo, that the invention claimed in the '659 patent was the subject of an offer for sale before the critical date. Helifix Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339 (Fed. Cir. 2000).

Section 102(b) provides, in relevant part, that "[a] person shall be entitled to a patent unless . . . the invention was . . . 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). The Supreme Court has established a two-prong test for the application of the on-sale bar: "First, the product must be the subject of a commercial offer for sale. . . . Second, the invention must be ready for patenting." Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 67 (1998). It is the first aspect of that test that primarily is at issue here.

A. Commercial Offer For Sale

We first consider, with particular attention to paragraph 2.14, whether part of the 1982 Enzo-Ortho agreement constituted a commercial offer for sale. Enzo argues that the agreement was solely for research purposes. It maintains that the general nature of the agreement was primarily research, citing paragraph 2.12, and it asserts that the parties' mere hope that a commercial project might result from the collaboration did not transform the research agreement into a commercial offer for sale. Enzo analogizes its facts to In re Kollar, 286 F.3d 1326 (Fed. Cir. 2002), in which we held that an agreement to conduct a broad research and development program was experimental rather than commercial. Additionally, Enzo asserts that paragraph 2.14 was not an enforceable offer for sale that occurred before the critical date. Enzo argues that paragraph 2.14 contains vague language, does not specifically require the sale of an embodiment of the '659 patent, and does not obligate Ortho to buy the "active ingredients" exclusively from Enzo.

Gen-Probe responds that paragraph 2.14 clearly relates to a commercial objective different from the research and development intent evident in paragraph 2.12 and other provisions of the agreement. It argues that the language of that paragraph constitutes a requirements contract that is enforceable, not illusory, because the parties have a duty to act reasonably and in good faith in setting prices and ordering goods.

We agree with Gen-Probe that paragraph 2.14 of the Enzo-Ortho agreement created the necessary contractual obligations on the parties to constitute a commercial offer for sale. See generally Group One, Ltd. v. Hallmark Cards, Inc., 254 F.3d 1041, 1046-48 (Fed. Cir. 2001) (discussing principles useful to determine whether a

communication or series of communications rises to the level of a commercial offer for sale). While it is true that the agreement states throughout its text that the parties are interested in cooperating in certain experimental work, the language of paragraph 2.14, unlike paragraph 2.12 and other provisions that explicitly refer to research and development efforts, does not purport to be for such preliminary production of the probe. Instead, paragraph 2.14 is distinctly different from those earlier sections because it relates specifically to supply of Ortho's worldwide requirements for what are clearly commercial purposes. Supply of worldwide requirements at reasonable times and prices surely means commercial supply, and the provision constitutes an offer to sell that has been accepted.

Enzo's reliance upon our decision in Kollar is misplaced. In that case, the research and development agreement at issue contained language that conveyed to the licensee an exclusive license under any issued patent "to design, engineer, construct, and operate a pilot plant and one or more commercial plants, to sell the resultant products, and to sublicense others." 286 F.3d at 1330. The agreement language was held to provide the "right to commercialize" the invention at issue and was essentially a license, not a sale, because it only contemplated that "resultant products" could potentially be sold, and did not offer to sell products of the claimed process. A key fact in that case was the fact that the involved invention was a process rather than a tangible item or product; we acknowledged that "[a] process is . . . not sold in the same sense as is a tangible item" because only the mere transfer of the know-how to carry out a given process has taken place and "the process has not been carried out or performed as a result of the transaction." Id. at 1332. An offer to sell a claimed product in being is quite

different from a license to an undeveloped claimed process. Accordingly, we concluded that the agreement was not a sale of the claimed invention and therefore was insufficient to raise a § 102(b) on-sale bar. Id. at 1331.

Here, in contrast, paragraph 2.14 of the Enzo-Ortho agreement cannot be considered to be only a research and development provision relating to an undeveloped process. Unlike the invention in Kollar, Enzo's claimed invention, the polynucleotide probe, is a tangible item or product that can be sold or offered for sale. The language of that provision clearly imposes upon Enzo the obligation to sell and on Ortho the obligation to purchase a significant percentage of its U.S. and worldwide requirements of the product labeled "Active Ingredients." There is no doubt that paragraph 2.14 constitutes a binding commitment by the parties to enter into a commercial sale and purchase relationship. Enzo's arguments to the contrary, citing the surrounding context of the agreement and the actual transfer of material between the parties, do little to alter the plain language of that provision in the agreement.

We have cautioned before that "[i]n any given circumstance, who is the offeror, and what constitutes a definite offer, requires looking closely at the language of the proposal itself. . . . Differing phrases are evidence of differing intent, but no one phrase is necessarily controlling." Group One, Ltd. v. Hallmark Cards, Inc., 254 F.3d 1041, 1048 (Fed. Cir. 2001) (citing Restatement (Second) of Contracts §§ 24, 26 (1981)). Here, the district court carefully considered the language of paragraph 2.14, and we discern no error in its legal interpretation or clear error in its factual findings. We thus agree with the district court that a binding contract was formed between Enzo and Ortho

and that the resulting commercial offer for sale, more than one year before the application for patent, ran afoul of the § 102(b) on-sale bar.

B. Identity of Material Shipped to Ortho

We next examine whether the sample that Enzo transferred to Ortho in December 1984 pursuant to the 1982 agreement was in fact the same material that Enzo deposited as ATCC 53411. Although the agreement lacked any explicit references to the '659 patent, the GC155 probe, or ATCC 53411, the district court concluded that Gen-Probe established that Enzo shipped GC155 pursuant to its obligations under that agreement, that GC155 was the same material as ATCC 53411, which was cited in the patent to support the patent's validity, and consequently that paragraph 2.14's offer for sale relates to an embodiment of the '659 patent.

Enzo argues that the polynucleotide allegedly sold or offered for sale before the critical date was not the subject matter of the '659 claims. It asserts that the polynucleotide delivered to Ortho consisted of "approximately 700 base pairs," according to shipping documents and laboratory notebooks, and thus differed from ATCC 53411, which contained 840 base pairs. Enzo also alleges that the district court erred as a matter of law by shifting the burden of production of evidence to Enzo to prove that the sample sent to Ortho was not the same as ATCC 53411, when it was Gen-Probe who bore the burden of establishing that there was a commercial sale of an embodiment of the claims of the '659 patent before the critical date.

In reply, Gen-Probe asserts that there is no real dispute that the Enzo-Ortho agreement related to the claimed invention. To link the patent to the agreement, and thus to the invalidating commercial offer for sale, Gen-Probe argues that the '659 patent

cites ATCC 53411 as a preferred embodiment, and that the GC155 probe and the probe deposited in the ATCC as sample 53411 are undisputedly identical. As for whether it was GC155 that Enzo delivered in December 1984 to Ortho pursuant to the 1982 agreement, Gen-Probe relies on laboratory notebooks and shipping documents accompanying the transferred material, as well as the testimony of Enzo's own scientists, to prove that the material was in fact GC155. The district court's burden-shifting, Gen-Probe argues, was proper because, following Gen-Probe's presentation of clear and convincing evidence that the probe delivered to Ortho was GC155, Enzo presented no evidence that the probe was not GC155, and that Enzo's mere arguments contesting the identity of the shipped material are insufficient to satisfy its burden of coming forward with evidence, so that summary judgment was proper.

We agree with the district court that there was no genuine issue of material fact as to whether the material that Enzo shipped to Ortho in December 1984 was GC155. Gen-Probe refers to several documents, including contemporaneous documents such as the shipping invoice and accompanying letters, that overwhelmingly refer to the material as "GC155" or simply "155." For example, the district court relied on a letter from Dr. Engelhardt, an Enzo employee, to his counterpart at Ortho stating that a probe specific to gonorrhea was being delivered pursuant to the 1982 agreement. It also cited laboratory notebooks describing a "155" insert as follows: "Works very nicely. Very clean. Sent three micrograms to Raritan [location of Ortho's New Jersey facilities]." The evidence also included Enzo quarterly reports from early 1984 that described Enzo's contractual obligation to deliver a GC probe to Ortho and that indicated that "the most promising" candidate was one designated "155-1." In short, Gen-Probe put forth a

great deal of evidence before the district court to establish that Enzo transferred GC155 to Ortho in satisfaction of the 1982 agreement.

Under Anderson v. Liberty Lobby, 477 U.S. 242 (1986), Enzo had the burden of showing that there was a genuine issue of material fact as to whether GC155 was shipped to Ortho. Id. at 250 ("Rule 56(e) provides that, when a properly supported motion for summary judgment is made, the adverse party 'must set forth specific facts showing that there is a genuine issue for trial.'" (footnote omitted)). We agree with the district court that Enzo's argument that the material was not GC155 because of an alleged discrepancy in the length of the base pairs failed to meet that burden. Since GC155 was transferred pursuant to the agreement, and that material has been shown to be the same as the ATCC deposit made to support the '659 patent, there was no genuine issue of material fact disputing that the subject matter of the agreement was the same as that of the patent.

We also reject Enzo's contention that the district court erred by shifting the burden of production to Enzo, the non-movant, and by calling upon Enzo to come forward with evidence to show that the question of the distinction between 700 and 840 base pairs was a genuine issue of material fact sufficient to defeat summary judgment. The Supreme Court stated in Anderson that "in ruling on a motion for summary judgment, the judge must view the evidence presented through the prism of the substantive evidentiary burden." 477 U.S. at 254. Although the ultimate burden of proof remained on Gen-Probe, once it came forward with evidence to establish that the material shipped to Ortho in December 1984 was GC155, it was proper for the district court to shift the burden of production of evidence to refute Gen-Probe's evidence to

Enzo. While it is true that a court must draw all reasonable inferences in favor of the nonmoving party, Enzo presented no evidence to the district court disputing the identity of the Ortho delivery. Instead, the court was faced only with Enzo's arguments and perhaps a suggestion of what Enzo might present at trial; that alone is insufficient to meet its burden of production. Attorney argument is no substitute for evidence. Although, as Enzo correctly stated at oral argument, a nonmoving party can defeat a motion for summary judgment by explaining why a party (Gen-Probe) with the burden of proof cannot meet its summary judgment standard, Enzo is mistaken that Gen-Probe has not met that hurdle. Once the district court determined that Gen-Probe satisfied its burden, and we agree that it did, it was incumbent upon Enzo, as the nonmoving party, to produce some evidence refuting Gen-Probe's claim. We find no error in the district court's reasoning, and we agree that Enzo failed to establish the existence of a genuine issue of material fact sufficient to avoid summary judgment.

C. Ready for Patenting

Regarding the second prong of the Pfaff test, Enzo argues that the district court erred in finding that the invention was ready for patenting. It asserts that Claim 1 of the patent recites an N. gonorrhoeae to N. meningitidis hybridization ratio of "greater than about five," and that because Enzo scientists were uncertain whether the probe that they shipped to Ortho would meet that ratio, the invention had not been fully reduced to practice. Gen-Probe responds that GC155 is a composition of matter and, according to Pfaff, is reduced to practice and hence ready for patenting when it is completely composed. It asserts that GC155 was a nucleotide sequence that fell within the claims, and had been isolated. Moreover, according to Gen-Probe, GC155 demonstrated

preferential hybridization with N. gonorrhoeae even before the December 1984 shipment, thereby satisfying the ratio requirements of the claims. Thus, Gen-Probe argues, GC155 was reduced to practice and ready for patenting.

We agree with Gen-Probe that GC155 was reduced to practice and therefore ready for patenting. We have held that reduction to practice is one way an invention may satisfy the ready for patenting condition. Sparton Corp. v. United States, 399 F.3d 1321, 1323 (Fed. Cir. 2005) (quoting Pfaff, 525 U.S. at 67-68). We reject Enzo's arguments that there was insufficient knowledge here about the probe to render it ready for patenting. The fact that Enzo scientists had shown that it did not cross-react with N. meningitides (thereby necessarily showing recognition of the specificity requirements set out by the ratios in the claims), and recognized its utility as a probe for N. gonorrhoeae, supports the conclusion that the probe that had been delivered to Ortho pursuant to the 1982 agreement had been reduced to practice. Moreover, the fact that CG155 was shown to be the same as an ATCC deposit made for the purpose of supporting the patent application also indicates that it was ready for patenting. We accordingly conclude that the district court properly found that the probe that Enzo delivered to Ortho was ready for patenting and thus satisfied the second prong of the Pfaff test.

D. Method Claims

Finally, Enzo argues that the district court erred by invalidating claims 5 and 6 of the '659 patent, which are characterized as "method" claims, by adopting a "gist of the invention" analysis. It alleges that the court improperly grouped those claims with product claims 1-4 and incorrectly invalidated all the claims together. Enzo asserts that

Gen-Probe did not prove that the offer to sell GC155 to Ortho could possibly invalidate claims 5 and 6. Gen-Probe responds that claims 5 and 6 were drafted in Jepson format and thus were an acknowledgement that they were patentable only insofar as they incorporate purportedly novel compositions for use in the hybridization test. Gen-Probe argues that because the compositions themselves were subject to a statutory bar, the so-called method claims 5 and 6 must also be unpatentable for the same reason.

We agree with Gen-Probe that the district court did not err in holding claims 5 and 6 invalid. The shipment to Ortho consisted not only of the GC155 probe, but also accompanying instructions as to how to use the probe in the hybridization assay. Moreover, given that the composition claims read on probes that hybridize with N. gonorrhoeae, carrying out such a hybridization assay is inseparable from the compositions themselves. Effectively, the offer to sell the compositions invalidates claims 5 and 6 based on those same probes. See generally In re King, 801 F.2d 1324, 1326 (Fed. Cir. 1986) (determining that an article of manufacture in the prior art can be used to support an anticipation rejection of method claims that, in essence, simply define what happens when that article of manufacture is placed in the environment in which the article will be used). Finally, Enzo has failed to meet its burden of coming forward with evidence tending to show that the detectable marker label was not present in the probe shipped to Ortho, and hence was not inherent in the offer to sell.

CONCLUSION

We have considered Enzo's remaining arguments and find them unpersuasive. Because Enzo offered for sale an embodiment of its claimed invention more than one year before the critical date of its '659 patent, the district court properly held that the

patent was invalid under the on-sale bar of 35 U.S.C. § 102(b). Accordingly, we affirm the court's judgment.

AFFIRMED