

United States Court of Appeals for the Federal Circuit

03-1464, 04-1099

CLONTECH LABORATORIES, INC.,

Plaintiff-Appellee,

v.

INVITROGEN CORPORATION
(formerly Life Technologies, Inc.),

Defendant-Appellant.

Marc R. Labgold, Patton Boggs LLP, of McLean, Virginia, argued for plaintiff-appellee. With him on the brief were Michael J. Schaengold, Richard J. Oparil, and Kevin M. Bell. Of counsel was Scott A.M. Chambers.

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Appealed from: United States District Court for the District of Delaware

Chief Judge Sue L. Robinson

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DECIDED: May 5, 2005

Before CLEVINGER, DYK, and PROST, Circuit Judges.

CLEVINGER, Circuit Judge.

Invitrogen Corporation appeals the judgment of the United States District Court for the District of Delaware holding that Invitrogen falsely marked certain of its molecular biology products. Clontech Labs., Inc. v. Invitrogen Corp., 263 F. Supp. 2d 780 (D. Del. 2003). Because the evidence does not support the court's finding that the relevant tests put Invitrogen on clear notice that certain products were not covered by the patents used to mark those products, we affirm-in-part, reverse-in-part, vacate-in-part, and remand for further proceedings consistent with this opinion.

This appeal arises from a 1998 lawsuit filed by Clontech Laboratories, Incorporated ("Clontech") against Invitrogen Corporation ("Invitrogen") (formerly Life Technologies, Incorporated) alleging, inter alia, false marking under 35 U.S.C. § 292.

The patents involved in the suit all claim priority to U.S. Patent Application No. 143,396, which was filed on January 13, 1988. The '396 application was continued as U.S. Patent Application 671,156, filed March 18, 1991, which issued as U.S. Patent No. 5,244,797 ("the '797 patent"). The '156 application was divided, giving rise to U.S. Patent Application No. 825,260, filed January 24, 1992, which issued as U.S. Patent No. 5,405,776 ("the '776 patent"). The '260 application was continued as U.S. Patent Application No. 404,907, filed March 15, 1995, and was again continued as U.S. Patent Application No. 614,260, filed March 12, 1996, which issued as U.S. Patent No. 5,668,005 ("the '005 patent"). The 614,260 application was continued as U.S. Patent Application No. 798,458, filed February 10, 1997, which issued as U.S. Patent No. 6,063,608 ("the '608 patent").

All four patents share the same title: "Cloned Genes Encoding Reverse Transcriptase Lacking RNase H Activity." The claims in all four patents are generally directed to RNase H deficient Reverse Transcriptase ("RT") polypeptides, see, e.g., the '797 patent (claim 1), the '608 patent (claim 1); polynucleotides encoding RT polypeptides, see, e.g., the '776 patent (claim 1), the '005 patent (claim 1), the '608 patent (claim 185); methods of using RTs to prepare DNA molecules, see, e.g., the '005 patent (claim 8), the '608 patent (claim 189); and kits for preparing DNA molecules using RTs, see, e.g., the '005 patent (claim 25), the '608 patent (claim 195).

Invitrogen markets RNase H deficient RTs known as SUPERSCRIPT ("SS") and SUPERSCRIPT II ("SSII"). 263 F. Supp. 2d at 786. SS and SSII are virally derived RTs either missing sequences important for RNase H activity, e.g., SS, or containing point mutations in regions of the RT coding sequence important for RNase H activity, e.g., SSII. Id. Invitrogen also produces and sells kits containing SSII as well as a wide variety of cDNA libraries purportedly made using SSII. Id. SS and SSII have been marked with all four patents. Id. at 788. In addition, the kits containing SSII and the many cDNA libraries have been marked with some of the patents at issue. See (J.A. at 2742-61).

II

Below, the parties disputed whether Invitrogen's SS, SSII, kits, and cDNA library products were falsely marked. In particular, the parties contested whether the patents at issue covered Invitrogen's many cDNA library products and whether the kits and SUPERSCRIPT products failed to meet the "substantially no RNase H activity" limitation of this family of patents, see, e.g., the '797 patent (claim 1), the '776 patent (claims 1 and 5), the '005 patent (claims 1, 8, 21, 30, and 34), and the alternative language of the most recent family member, the '608 patent, see, e.g., claim 1 ("substantially reduced RNase H activity"), claim 3 ("no detectable RNase H activity"), claim 24 ("does not significantly degrade an mRNA template"), claim 31 ("no detectable RNase H activity").

The trial court held that Invitrogen's SS, SSII, kits, and cDNA library products had been falsely marked with the patents in suit. 263 F. Supp. 2d at 793. The trial court determined that "[n]one of Invitrogen's patents in suit are directed to cDNA libraries," id. at 790, and that the claim limitation "substantially no RNase H activity," as used in this

family of patents, was defined in the written description. Id. at 785. Specifically, the court concluded that the written description defines "substantially no RNase H activity" in terms of an assay that measures how active a nearly pure population of RT polypeptides is at cutting RNA:

By the terms 'substantially no RNase H activity' is intended reverse transcriptase purified to near homogeneity and having an RNase H activity of less than 0.001 pmoles [³H](A)_n solubilized per μg protein with a [³H](A)_n(dT)_n substrate in which the [³H](A)_n [sic] has a specific radioactivity of 2,200 cpm/pmole. RNase H activities of this specific activity or less allows the preparation of cDNA without significant degradation of the mRNA template during first-strand synthesis.

The '797 patent, col. 9, ll. 14-22; see also the '776 patent, col. 9, ll. 14-22; the '005 patent, col. 9, ll. 19-27; the '608 patent, col. 9, ll. 21-29.¹ The court did not distinguish between the "substantially no RNase H activity" used in the claims of the '797, '776, and '005 patents and the alternative language used in the claims of the '608 patent.

Interpreting 35 U.S.C. § 292, the trial court placed the burden on Clontech to prove four elements: "(1) a marking importing that an object is patented (2) falsely affixed to (3) an unpatented article (4) with intent to deceive the public." 263 F. Supp. 2d at 791. Then the court considered these elements in light of evidence pertaining to Invitrogen's products and patents as well as several RNase H activity experiments performed over the life of this patent family by the inventors and other Invitrogen scientists and experts. Id. at 787-88, 792-93. The evidence included experimental results from solubilization and gel assays performed in 1990, 1991, 1996, and 2000. Id. at 787-88. In contrast to the earlier experiments, the 2000 experiments were performed

¹ According to the parties, the correctness of this definition has been stipulated to for the '797 patent, the '776 patent, and the '005 patent.

using the solubilization assay defined in the written description for the "express purpose" of determining whether Invitrogen's SS and SSII meet the limitation of "substantially no RNase H activity." Deciding that the 2000 experiments were dispositive, the court found that "[a]t the very least, these tests put [Invitrogen] on notice that its products were not covered by the patents in suit and any good faith belief that [Invitrogen] had that its products were covered by the patents was lost." *Id.* at 793. The court reasoned that after this notice, "[Invitrogen's] failure to correct its mistaken mismarking of its products rose to the level of deceptive intent." *Id.* Accordingly, the court held Invitrogen liable for falsely marking its products in violation of 35 U.S.C. § 292.

Invitrogen appeals, arguing that the trial court miscomprehended the legal standard applicable to the element of intent to deceive, committed clear factual error in interpreting the results of the 2000 experiments, and erred by interpreting 35 U.S.C. § 292 as prohibiting marking where the patent does not cover the product at issue. Clontech responds, arguing that the trial court applied the correct legal standards and did not err in its interpretation of the 2000 test results. We have jurisdiction to hear this case pursuant to 28 U.S.C. § 1338(a) (2000) and 28 U.S.C. § 1295(a)(1) (2000).

III

We begin with the statute in suit, which provides that:

Whoever marks upon, or affixes to, or uses in advertising in connection with any unpatented article, the word 'patent' or any word or number importing that the same is patented for the purpose of deceiving the public . . . [s]hall be fined not more than \$500 for every such offense.

35 U.S.C. § 292(a) (2000).

The case law of this circuit on the statute in suit is sparse. In fact, only one precedent has substantively addressed the statute, and in that case, we affirmed, without discussion of the text of the statute, the trial court's holding that no violation of the statute had occurred because the plaintiff failed "to produce any evidence of intent to deceive the public." Arcadia Mach. & Tool, Inc. v. Sturm, Ruger & Co., 786 F.2d 1124, 1125 (Fed. Cir. 1986). Consequently, this case presents us with virtually an issue of first impression.

The statute supplies a civil fine for false marking of articles. Id. at 1125. According to the statute, when an unpatented article is marked with the word "patent" or any word or number that imports that the article is patented, and such marking is for the purpose of deceiving the public, the fine is invoked. When the statute refers to an "unpatented article" the statute means that the article in question is not covered by at least one claim of each patent with which the article is marked. Thus, in order to determine if an article is "unpatented" for purposes of section 292, it must be first determined whether the claims of a patent cover the article in question. To make that determination, the claim in question must be interpreted to ascertain its correct scope, and then it must be ascertained if the claim reads on the article in question.

Assuming an article is mismarked as "patented" because the claims of the cited patent do not read on the article, the question arises whether more is required by way of proof to establish that the mismarking is for the purpose of deceiving the public. That is, should the statute be read to cause all actual mismarking to be subject to the civil fine?

This question has been addressed and answered in other circuits. For example, the Court of Appeals for the First Circuit long ago interpreted a predecessor statute in

London v. Everett H. Barr Corporation, 179 F. 506 (1st Cir. 1910). The earlier statute outlawed marking an unpatented article with the word "patent" for the purpose of deceiving the public. The First Circuit recognized, even then, that interpreting claims is not an exact science, and that consequently where one "has an honest, though mistaken, belief that upon a proper construction of the patent it covers the article which he marks," the requisite intent to deceive the public would not be shown. Id. at 510. Years later, the Court of Appeals for the Fifth Circuit adopted the formulation that an honest, though mistaken, mismarking of an article would not trigger liability under the statute. See Brose v. Sears, Roebuck and Co., 455 F.2d 763, 768-69 (5th Cir. 1972).

We see no reason to interpret the statute differently to render it a statute of strict liability for mismarking. Intent to deceive is a state of mind arising when a party acts with sufficient knowledge that what it is saying is not so and consequently that the recipient of its saying will be misled into thinking that the statement is true. Seven Cases of Eckman's Alternative v. United States, 239 U.S. 510, 517-18 (1916). Intent to deceive, while subjective in nature, is established in law by objective criteria. Id. Thus, "objective standards" control and "the fact of misrepresentation coupled with proof that the party making it had knowledge of its falsity is enough to warrant drawing the inference that there was a fraudulent intent". See Norton v. Curtiss, 433 F.2d 779, 795-96 (CCPA 1970). Thus, under such circumstances, the mere assertion by a party that it did not intend to deceive will not suffice to escape statutory liability. Such an assertion, standing alone, is worthless as proof of no intent to deceive where there is knowledge of falsehood. But in order to establish knowledge of falsity the plaintiff must show by a preponderance of the evidence that the party accused of false marking did not have a

reasonable belief that the articles were properly marked (i.e., covered by a patent).

Absent such proof of lack of reasonable belief, no liability under the statute ensues.

In this case, the trial court examined the facts pertaining to the tests conducted in 2000, and concluded that those tests put Invitrogen on notice that its products were not covered by the patents and that its markings were, therefore, statutorily deceptive. The trial court also determined that Invitrogen had no basis for asserting through its labeling that its kits and cDNA library products were "patented" and that Invitrogen's products were falsely marked for the purpose of deceiving the public.

The question of whether conduct rises to the level of statutory deception is a question of fact, see, e.g., Kangaroos U.S.A., Inc. v. Caldor, Inc., 778 F.2d 1571, 1573 (Fed. Cir. 1985), and when that question is resolved as here in a bench trial, we review the decision of the trial court for clear error. B.F. Goodrich Co. v. Aircraft Braking Sys. Corp., 72 F.3d 1577 (Fed. Cir. 1996).

IV

On appeal, Clontech does not challenge the trial court's finding of no intent to deceive as to the period before the year 2000. But Clontech urges that the trial court correctly found that the 2000 tests showed that Invitrogen had knowledge that the labeled products were not covered by the patents. Invitrogen makes two arguments in response.²

² Invitrogen has a third argument, which it contends is a blanket defense to all charges of false marking. The argument is based on the district court's findings that employees "unfamiliar with the patent laws" honestly believed the products to be correctly marked. See 263 F. Supp. 2d at 788-89, 792-93. This of course is preposterous. As we note, supra, the inference of intent to deceive cannot be defeated with blind assertions of good faith where the patentee has knowledge of mismarking.

First, Invitrogen asserts that the results of the experiments performed in 2000 do not clearly show that the RNase H activity of SS and SSII fail to meet the limitation of "substantially no RNase H activity." In other words, argues Invitrogen, the trial court misinterpreted the results of the 2000 experiments. Second, according to Invitrogen, even if it knew that SS and SSII could not meet the "substantially no RNase H activity" limitation, it cannot be liable for false marking with the '608 patent because the claims of the '608 patent define the limiting levels of RNase H activity using different language. The clear error standard permits reversal where after review we are "left with the definite and firm conviction that a mistake has been committed." United States v. United States Gypsum Co., 333 U.S. 364, 395 (1948); Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1275 (Fed. Cir. 2004). We address each argument in turn.

A

After evaluating the trial court's opinion, the testimony and evidence, and the parties' arguments, we are convinced that the trial court clearly erred when it concluded that the results of the 2000 experiments put Invitrogen on clear notice that its RTs, i.e., SS and SSII, have RNase H activity greater than "substantially no RNase H activity" as that term is defined by the trial court's claim interpretation.

As noted above, the trial court found, and the parties do not dispute, that the 2000 experiments were performed to determine whether SS and SSII meet the assay-defined "substantially no RNase H activity" limitation of the claims of the patents in suit. 263 F. Supp. 2d at 787-88. The 2000 experiments were performed by Dr. Gerard, an Invitrogen scientist who is an inventor listed on the patents in suit, and Dr. Champoux,

an Invitrogen expert for the litigation. The RTs tested were SS, SS(R8),³ and SSII. The disputed evidence consists of Dr. Gerard's notebook pages (J.A. at 3202-22), which contain raw data as well as Dr. Gerard's notes pertaining to that data, and Dr. Champoux's summary of his analysis of the data (Id. at 3223). Both scientists testified.

Dr. Gerard's handwritten notes reveal an analysis of the raw data. In particular, the notes reflect that of fourteen SS, SS(R8), or SSII experiments, five showed RT RNase H activity higher than the claimed 0.001 picomoles [³H](A)_n solubilized per µg protein. At trial, however, Clontech elicited testimony on two data points, one for SS, which showed RNase H levels of approximately 44 times the claimed amount, and one for SSII, which showed activity of approximately 16 times the claimed amount. (Id. at 5268-69).

Invitrogen does not appear to have addressed this on redirect. Instead, Invitrogen relied on Dr. Champoux, the expert it retained for the testing to interpret the data generated from the 2000 experiments. Dr. Champoux testified that the 2000 experiments showed that the tested RTs had "no detectable RNase H activity." (Id. at 5675). Dr. Champoux also testified about how the tests were designed and his involvement in designing the tests. (Id. at 5678-82). He also explained that his calculations took into account variability resulting from the series of measurements that go into a sample. (Id. at 5684-91). He explained that when properly interpreted the 2000 tests showed that in 13 of the 14 experiments performed RNase H activity was no

³ Invitrogen characterizes SS(R8) as a "second sample" of SUPERSCRIPT. Clontech does not argue that there is any important difference between SS and SS(R8) or that it is otherwise inappropriate to consider SS(R8) as equivalent to SS.

different in the presence of SS, SS(R8), or SSII, than in the absence of RTs. (Id. at 5692-63). Finally, Dr. Champoux explained that the interpretation of the data seen in Dr. Gerard's notes was not reliable because it did not take into account experimental variation. (Id. at 5696-98). After reiterating his conclusion that the data showed no difference between samples with RNase H deficient RTs and background, (Id. at 5698), he finally explained that the one test of the 14 that was aberrant was likely due to a contaminating "bacterial RNase H in that preparation." (Id. at 5701).

This testimony went largely unanswered. Clontech's expert provided a hypothesis that some data points, including those showing RNase activity, were reliable because they occurred in the first day of testing but that data points from later days were unreliable because freezing and thawing caused the enzyme activity to degrade with time. However, this criticism was answered by Dr. Champoux who explained that the experiments used the standard technique of storing the RT enzymes in glycerol to protect against freezing-related damage. (Id. at 5676).

As noted above, the standard is whether Clontech proved by a preponderance of the evidence that Invitrogen did not have an honest good faith belief in marking its products. The trial court held that prior to the 2000 experiments, there was insufficient evidence to find that Invitrogen did not have a good faith belief that SS and SSII met the "substantially no RNase H activity" limitation.⁴ Thus, the issue is whether the results of the 2000 experiments should have disabused Invitrogen of any good faith belief it harbored concerning the RNase H activity of SS and SSII. Viewing the testimony and evidence as a whole, we are firmly convinced the court erred in deciding that the results

⁴ This holding is not appealed by Clontech.

defining RNase H activity as the same in each instance, the holding cannot stand for the reasons discussed above, i.e., Clontech did not prove that the results of the 2000 experiments put Invitrogen on notice that SS and SSII do not meet the "substantially no RNase H activity" limitation. If, on the other hand, the court gave the language some other construction, absent a statement of what the construction is and how that construction applies to the evidence, we are in no position to review that decision. For that reason, we vacate the trial court's finding that SS and SSII were falsely marked with the '608 patent.

V

In its next challenge, Invitrogen insists that the trial court's "finding that Invitrogen's cDNA libraries were falsely marked was legally erroneous." Factually, Invitrogen does not contend that its cDNA library products⁵ fall within the boundaries of the properly construed claims of any of the four patents at issue. We thus accept the trial court's holding on that issue. Moreover, Invitrogen does not contend that it had a good faith belief that its cDNA library products fall within the boundaries of the properly construed claims or that its products were marked by mistake. Instead, Invitrogen relies

⁵ The Joint Appendix contains a list of products that the parties stipulate are marked with particular patents. This list appears to contain approximately 69 cDNA library products, many marked with the '005 patent and/or the '608 patent. Both of these patents contain claims generally directed to making cDNA molecules from an mRNA template using RTs. See the '005 patent (claim 8); the '608 patent (claim 189). Although information sheets for all of Invitrogen's library products are not in the record, some that are contain the language: "This product is the subject of U.S. Patent No. 5,668,005, owned by [Invitrogen]. Purchase of this product conveys to the buyer only the non-transferable right under to use the product in research conducted by the buyer. The buyer cannot sell or otherwise transfer this product to any third party." (J.A. at 1237); see also (J.A. at 1249, 1263-65) ("This product is the subject of U.S. Patent No. 5,668,005.").

"This product is the subject of U.S. Patent No. 5,668,005." See, e.g., (J.A. 1263-65). Moreover, Invitrogen does not appear to have challenged the trial court's claim construction that its claims did not cover the libraries. At trial, Clontech received a claim construction that: "[n]one of Invitrogen's patents in suit are directed to cDNA libraries." 263 F. Supp. 2d at 790. Invitrogen does not point this court to where it urged a different claim interpretation on the trial court that was erroneously rejected. Applying that claim construction, the trial court held that "Invitrogen's cDNA libraries are not covered by the patents in suit." Id. at 790. Beyond blind assertions of good faith, Invitrogen does not direct this court to trial evidence that it had an objective good faith belief that its cDNA library products are patented as that term is used in section 292. Instead, Invitrogen now asks us to construe the claims to include SSII, to find that SSII meets some or all of the limitations of the '005 and '608 patents pertaining to RNase H activity, to construe the limitations of the '005 and '608 patents pertaining to cDNA synthesis, to find that SSII meets the limitations of the '005 and '608 patents pertaining to cDNA synthesis, to find that Invitrogen's cDNA libraries were made with the methods claimed by the '005 and '608 patents, and to find that Invitrogen could assert a patent infringement claim if others were to either make cDNA library products using RNase H deficient RTs or use Invitrogen's existing cDNA library products without its permission.

We will not decide these many issues for the first time on appeal. For the purposes of this appeal, Invitrogen has effectively waived these arguments by failing to raise them in a form that required a decision by the trial court. See Fuji Photo Film Co. v. Jazz Photo Corp., 394 F.3d 1368, 1377 (Fed. Cir. 2005).

VII

For clarity, we begin our summary with a statement of what we are not reviewing. We are not reviewing and offer no opinion on whether Invitrogen's SS and SSII RTs meet the limitations of any of the claims in any of the patents, or whether if those RTs are covered by claims, those claims would be not invalid. Neither are we considering any other question of patent scope, validity, or enforceability of any of the patents at issue.

What we are reviewing is the trial court's judgment that Invitrogen falsely marked SS and SSII RTs because it knew that those products did not meet the "substantially no RNase H activity" limitation of the '797, '776, and '005 patents or similar limitations of the '608 patent; falsely marked cDNA library products with the patents in suit (most frequently the '005 patent and the '608 patent); and falsely marked its kit products with the patents in suit.

Keeping the above in mind, because we discern clear error in the trial court's finding that the 2000 tests put Invitrogen on notice that SS and SSII do not meet the "substantially no RNase H limitation," we reverse the finding that SS and SSII were falsely marked based on claims containing that limitation. Furthermore, because the trial court gave no indication that the claims of the '608 patent contained the limitation "substantially no RNase H activity" or that Invitrogen had knowledge that SS and SSII failed to meet similar (but not identical) limitations present in the claims of the '608 patent, we vacate and remand the decision of the trial court finding false marking of SS and SSII with the '608 patent for further proceedings consistent with this opinion.

Because Invitrogen's policy arguments are unconvincing and foreclosed by statute, we affirm the trial court's decision that Invitrogen falsely marked its cDNA library products.

Regarding Invitrogen's kit products, if the decision that Invitrogen engaged in false marking is founded in the clearly erroneous finding that the 2000 tests put Invitrogen on notice that SS and SSII do not meet the "substantially no RNase H limitation," it is reversed. If the trial court had other reasons for reaching its decision, it may treat this decision as a remand to more fully explain its reasoning.

For the reasons discussed above, we affirm-in-part, reverse-in-part, vacate-in-part and remand for further proceedings consistent with this opinion.

COSTS

No costs.

AFFIRM-IN-PART, REVERSE-IN-PART, VACATE-IN-PART AND REMAND