NOTE: This disposition is nonprecedential

United States Court of Appeals for the Federal Circuit

ELI LILLY AND COMPANY,
Plaintiff-Appellant,

v.

ACTAVIS ELIZABETH LLC,
Defendant-Appellee,

AND

SUN PHARMACEUTICAL INDUSTRIES, LTD.,
Defendant-Appellee,

AND

SANDOZ, INC.,
Defendant-Appellee,

AND

MYLAN PHARMACEUTICALS INC.,
Defendant-Appellee,

AND

APOTEX INC.,
Defendant-Appellee,

AND

AUROBINDO PHARMA LTD.,
Defendant-Appellee,

AND

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Appellee.

2010-1500

Appeal from the United States District Court for the District of New Jersey in Case No. 07-CV-3770, Judge Dennis M. Cavanaugh.

Decided: July 29, 2011

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Before NEWMAN, FRIEDMAN,[*] AND LOURIE, *Circuit Judges*.

NEWMAN, *Circuit Judge*.

This case arises on the filing by each of the defendants of an Abbreviated New Drug Application (ANDA), accompanied by a Hatch-Waxman Act "Paragraph IV certification" challenging the validity and enforceability and asserting non-infringement of United States Patent No. 5,658,590 (the '590 patent) owned by Eli Lilly and Company. The '590 patent is directed to the use of the drug atomoxetine to treat attention-deficit/hyperactivity disorder (ADHD). Lilly obtained federal regulatory approval from the Food and Drug Administration (FDA), and markets the product for

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[*] Circuit Judge Friedman heard oral argument in this appeal, but died on July 6, 2011 and did not participate in the final decision. The case was decided by the remaining judges of the panel, in accordance with Fed. Cir. Rule 47.11.

this use, with the brand name Strattera®. The defendants seek to sell generic counterparts of this drug before the expiration date of the '590 patent.

The United States District Court for the District of New Jersey sustained the '590 patent against the defendants' challenges on the grounds of inequitable conduct, anticipation, obviousness, and non-enablement. However, the court held the claims invalid for lack of utility, which the court called "enablement/utility." The court also held that if the claims were valid the defendants would be liable for inducement to infringe, but that they would not be liable for contributory infringement. The ruling of invalidity for lack of utility, and the ruling that contributory infringement does not also apply, are reversed. The district court's other rulings are affirmed.[1]

I

THE PATENTED INVENTION

The '590 patent is directed to the use of the compound tomoxetine,[2] having the chemical name (R)-(–)-N-methyl-3-(2-methylphenoxy)-3-phenylpropylamine, for treatment of ADHD. Claim 1 is as follows:

> 1. A method of treating attention-deficit/hyperactivity disorder comprising administering to a patient in need of such treatment an effective amount of tomoxetine.

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[1] *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 676 F. Supp. 2d 352 (D.N.J. 2009); 731 F. Supp. 2d 348 (D.N.J. 2010).

[2] The common names "atomoxetine" and "tomoxetine" are both used in the record, and are used herein as they appear in the record.

Claim 1 was treated by the parties and the district court as dispositive of the issues. At the time the '590 patent application was filed, tomoxetine was a known compound, described and claimed in Lilly's U.S. Patent No. 4,314,081, issued February 2, 1982. Tomoxetine was studied through Phase II clinical trials for the treatment of urinary incontinence, and through Phase III clinical trials for treatment of depression. *See* 21 C.F.R. §312.21 (explaining Phase I, Phase II, and Phase III clinical trial criteria). Although the clinical trials showed that tomoxetine was safe for human use, the product did not provide the medicinal benefits for which it was being evaluated.

In 1993 Lilly scientists Dr. John Heiligenstein and Dr. Gary Tollefson suggested that tomoxetine might be effective for treatment of ADHD. ADHD is a complex neurobiological disorder characterized by developmentally inappropriate levels of inattention, hyperactivity, and impulsiveness. The district court explained that the occurrence of ADHD is wide, the cause is unknown, and the mechanism of drug treatment is unclear. *Eli Lilly*, 731 F. Supp. 2d at 352-53, 366. It was explained at the trial that research concerning ADHD is difficult because there is no animal model for experimental evaluation of the effect of any particular treatment.

At the time of this invention, all of the products that were being used to treat ADHD exhibited deficiencies. The '590 patent explains that the stimulants that were being used require multiple doses per day, produce a rebound effect between doses, and cause undesirable side effects; and the tricyclic antidepressants that were being used also produce undesirable side effects, and require careful supervision and dosage titration. The record states that the suggestion of Drs. Heiligenstein and Tollefson that tomoxetine might be an effective treatment for ADHD was met with

skepticism. However, arrangements were made to conduct clinical tests at Massachusetts General Hospital, and on December 1, 1994 the investigators submitted to the FDA an Investigational New Drug (IND) application for treatment of ADHD with tomoxetine. On January 3, 1995 the FDA authorized the investigation. The '590 patent application was filed on January 11, 1995, and the clinical investigation commenced. By May 1995 initial positive results were obtained, and in October 1995 the investigators reported their preliminary results at a meeting of the American Association of Child and Adolescent Psychiatry.

Clinical investigation continued over the next seven years, including treatment of patients of various ages and ADHD severity, determination of possible side effects and of the cumulative effect of treatment, the development and evaluation of formulations, schedules, and dosages, and other studies relevant to determination of efficacy and safety. On November 26, 2002 the FDA approved the use of tomoxetine for treatment of ADHD in adults, children, and adolescents, at dosages of 10, 18, 25, 40, and 60 mg/day of oral administration; on February 14, 2005 the FDA also approved dosages of 80 and 100 mg/day. The record states that the product has achieved wide use.

II

OBVIOUSNESS

The defendants challenged patent validity on the ground of obviousness, arguing that atomoxetine was a known norepinephrine inhibitor and thus that it would have been obvious to test this product for treatment of ADHD. The defendants argued that the inventors simply "substituted one potent selective norepinephrine reuptake inhibitor (atomoxetine) for another (desipramine) known to be effec-

tive in treating ADHD." *Eli Lilly*, 731 F. Supp. 2d at 356 (quoting Defendants' Post-Trial Brief, at 7).

The district court, discussing this argument, referred to the reports of sudden death of children taking desipramine, and found that these "negative reports concerning desipramine. . . . must weigh to some extent away from using atomoxetine as a potential ADHD treatment" although "desipramine was functionally a similar compound to atomoxetine." *Id.* at 365. The court found that "while the prior art demonstrated that norepinephrine reuptake inhibition was relevant to ADHD treatment, the literature does not appear to indicate that it was alone sufficient." *Id.* at 362. The court stated that "it is impermissible to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *Id.* at 365-66 (quoting *In re Weslau*, 353 F.2d 238, 241 (CCPA 1965)).

The district court observed that the entirety of the prior art must be considered in determining obviousness. There was no evidence that the advantageous and effective properties of atomoxetine to treat ADHD, devoid of the negative effects of known and similar products, would have been obvious from the prior art. The district court found that treatment of ADHD with atomoxetine would not have been predicted by skilled artisans with a reasonable degree of certainty, and concluded that there was not clear and convincing evidence that the effective use of atomoxetine to treat ADHD would have been obvious to a person of ordinary skill in the field of the invention.

The defendants argue that, at the very least, it would have been "obvious to try" atomoxetine for this use. However, applying the guidance of *KSR International Co. v.*

Teleflex Inc., 550 U.S. 398 (2007), there was no evidence that use of atomoxetine had been identified as a possible solution to the problems of treating ADHD, nor that the exercise of common sense would have led a person of ordinary skill to test atomoxetine for treatment of ADHD. *See id.* at 420-21. The evidence was contrary to the likelihood that atomoxetine would be effective to treat ADHD, for atomoxetine was known not to be an effective antidepressant, and the known norepinephrine inhibitor despiramine was associated with sudden death in children. The experts for both sides were in agreement that they would not have expected that atomoxetine would be a successful treatment of ADHD.

We discern no error in the district court's ruling that the claims had not been proved invalid on the ground of obviousness.

III

ENABLEMENT/SCOPE

The defendants argue that the '590 specification does not enable the full scope of claim 1, pointing out that the claim's words "administering to the patient an effective amount" are not limited to the formulations that are specifically exemplified in the specification. The defendants argue that the patent enables only the immediate release products and dosages in the specific examples, and that claim 1 is invalid because it is not so limited. The defendants' expert witness testified that formulations and dosages for treatment of ADHD are not routine, and thus that undue experimentation would be required to determine the specific formulation and effective amount to be administered to a specific patient.

The '590 patent describes the formulation and administration of tomoxetine as follows:

> Since tomoxetine is readily orally absorbed and requires only once/day administration, there is little or no reason to administer it in any other way than orally. It may be produced in the form of a clean, stable crystal, and thus is easily formulated in the usual oral pharmaceutical forms, such as tablets, capsules, suspensions, and the like. The usual methods of pharmaceutical scientists are applicable. It may be usefully administered, if there is any reason to do so in a particular circumstance, in other pharmaceutical forms, such as injectable solutions, depot injections, suppositories and the like, which are well known to and understood by pharmaceutical scientists. It will substantially always be preferred, however, to administer tomoxetine as a tablet or capsule and such pharmaceutical forms are recommended.

'590 patent, col. 2 ll.20-33. The patent's description of dosages for treatment of ADHD with tomoxetine includes:

> The effective dose of tomoxetine for ADHD is in the range from about 5 mg/day to about 100 mg/day. The preferred adult dose is in the range from about 10 to about 80 mg/day, and a more highly preferred adult dose is from about 20 to about 60 mg/day. The children's dose of course is smaller, in the range from about 5 to about 70 mg/day, more preferably from about 10 to about 50 mg/day. The optimum dose for each patient, as always, must be set by the physician in charge of the case, talking into account the patient's size, other medications which the pa-

> tient requires, severity of the disorder and all of the other circumstances of the patient.

Id. at col. 2 ll.7-19.

The district court found that "the various conceivable formulations are standard—and they were not part of the basis for the invention's patentability." *Eli Lilly*, 731 F. Supp. 2d at 375. The court observed that the particular dosage form is not the invention, and is routinely determined:

> a dosage formulator as defined by the parties—a scientist with at least a bachelor's degree in pharmacy or some closely related field, at least three to five years of work experience in developing a particular pharmaceutical dosage form, and the ability to consult with others skilled in other particular disciplines (e.g., physicians, analytical chemists, and biopharmaceutical scientists)—would be able to do so without undue experimentation.

Id. at 376. In *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988), this court identified several factors that may assist in determining whether experimentation is "undue":

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

858 F.2d at 737. The district court applied this precedent, and concluded that "reliance on formulation-related disclo-

sures in the prior art [is] appropriate." *Eli Lilly*, 731 F. Supp. 2d at 375.

The defendants cite *ALZA Corp. v. Andrx Pharmaceuticals LLC*, 603 F.3d 935 (Fed. Cir. 2010), in which this court found that the patent did not "provide sufficient guidance for a person of ordinary skill in the art to make the non-osmotic dosage forms as claimed." *Id.* at 940. However, in that case the court described the field of ascending release dosage forms as "not mature" and "a 'breakaway' from the prior art." *Id.* at 941. Such characteristics were not here demonstrated. There was no evidence that known procedures for determination of dosages and formulation did not apply. *See Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987) ("A patent need not teach, and preferably omits, what is well known in the art.").

Enablement is not negated if a reasonable amount of experimentation is required to establish dosages and formulation of an active ingredient. *See Enzo Biochem, Inc. v. Calgene Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999). Lack of enablement must be proved by clear and convincing evidence. *Auto. Tech. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1281 (Fed. Cir. 2007). Error has not been shown in the district court's finding and conclusion that the scope of the claims is enabled. That ruling is affirmed.

IV

ENABLEMENT/UTILITY

The district court held all of the '590 patent claims invalid for lack of "enablement/utility." The court held that utility was not established because experimental data showing the results of treatment of ADHD were not included in the specification. The court held that "the court

cannot conclude that a person of skill in the art would have recognized the method of treatment's utility in view of the specification and prior art." *Eli Lilly*, 731 F. Supp.2d at 389.

The patent statute requires that the specification "disclose as a matter of fact a practical utility for the invention." *In re Ziegler*, 992 F.2d 1197, 1201 (Fed. Cir. 1993). Lilly points out that the utility to treat ADHD was fully disclosed and correctly described and enabled in the specification. The '590 patent describes the use of tomoxetine to treat ADHD in humans, and states that "tomoxetine is a notably safe drug, and its use in ADHD, in both adults and children, is a superior treatment for that disorder because of improved safety." Col.1 ll.66 to col.2 l.1. The patent refers to the two recognized types of ADHD, inattentive type and hyperactive-impulsive type, and states: "Treatment with tomoxetine is effective in patients who are primarily suffering from either component or from the combined disorder." Col.3 ll.38-40. The patent states:

> The method of the present invention is effective in the treatment of patients who are children, adolescents or adults, and there is no significant difference in the symptoms or the details of the manner of treatment among patients or different ages.

Col.4 ll.14-18. No criticism of the correctness of these statements has been offered. The defendants do not dispute that the '590 patent describes the utility of tomoxetine for treatment of ADHD, and that the utility is correctly described. Lilly agrees that human test data were not available at the time the patent application was filed, because human tests were prohibited without FDA authorization.

Dr. Heiligenstein, one of the inventors, testified about his uncertainty whether this treatment of ADHD would be effective, when he and Dr. Tollefson suggested experimental testing for this purpose:

> Q: At the time of this filing, did you have a reasonable expectation that tomoxetine would work to treat ADHD?
>
> A: It was a hypothesis.
>
> Q: Did you have a reasonable expectation?
>
> A: Reasonable? Can you define reasonable?
>
> Q: Did you believe it was going to work for ADHD?
>
> A: No, I wasn't sure at all that it would work.

Heiligenstein Dep. 127:4-12, August 7, 2008. It was not disputed that persons experienced in this field would require actual human tests to verify the effectiveness of this use. As the Court discussed in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593 (1993): "Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from the other fields of human inquiry." (quoting Michael D. Green, 86 Nw. U. L. Rev. 643, 645 (1992)).

Although it was recognized that Dr. Heiligenstein's hypothesis required testing, Lilly points out that support for the testing was provided, patent procedures were initiated, and the FDA authorized proceeding with human clinical trials. The Manual of Patent Examining Procedure instructs examiners to give presumptive weight to the utility for which human trials have been initiated:

> MPEP §2107.03 (8th ed. 2008). IV. . . . Before a drug can *enter* human clinical trials, the sponsor, often the applicant, must provide a convincing rationale to those *especially* skilled in the art (e.g., the Food and Drug Administration) that the investigation may be successful. Such a rationale would provide a basis for the sponsor's expectation that the investigation may be successful. In order to determine a protocol for phase I testing, the first phase of clinical investigation, some credible rationale of how the drug might be effective or could be effective would be necessary. *Thus, as a general rule, if an applicant has initiated human clinical trials for a therapeutic product or process, Office personnel should presume that the applicant has established that the subject matter of that trial is reasonably predictive of having the asserted therapeutic utility*.

(Emphases in original.) During examination of the '590 application, the patent examiner did not require the submission of data showing treatment of ADHD with atomoxetine, although it is not disputed that such data were obtained shortly after the patent application was filed. The utility of this product to treat ADHD is not so incredible as to warrant the special procedures that are authorized for use when the examiner doubts the described utility, as in *In re Swartz*, 232 F.3d 862 (Fed. Cir. 2000) (cold fusion); *Newman v. Quigg*, 877 F.2d 1575, *modified* 886 F.2d 329 (Fed. Cir. 1987) (perpetual motion); and for subject matter in once notoriously intractable areas such as cures for baldness or cancer. In deciding whether additional information is required for examination purposes, deference is owed to the "qualified agency presumed to have properly done its job." *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984).

In this case, evidence of the described utility of tomoxetine was not requested by the patent examiner, although experimental verification was obtained soon after the filing of the patent application. The examination of the '590 patent was in accordance with the rules, as the court has explained:

> [A] specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented *must* be taken as sufficient to satisfy the utility requirement of §101 for the entire claimed subject matter *unless* there is reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

In re Langer, 503 F.2d 1380, 1391 (CCPA 1974) (emphases in original). In *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995) the court again explained that:

> A specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of §112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

51 F.3d at 1566 (quoting *In re Marzocchi*, 439 F.2d 220, 223 (CCPA 1971)) (emphases in original). In *Brana*, where the utility was antitumor activity in humans, the court reaffirmed the practice that: "Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to

convince such a person of the invention's asserted utility." *Id.* at 1566 (citing *In re Bundy*, 642 F.2d 430, 433 (CCPA 1981)). Such evidence was not here provided by the PTO, and rebuttal evidence was not required.

The district court's statement that "there was no credible disclosure of utility to begin with," *Eli Lilly*, 731 F. Supp. 2d at 386 n.18, does not comport with the specification's extensive disclosure of utility. The district court appears to have accepted the defendants' argument that in view of the absence of experimental data in the specification, the disclosed utility must be deemed incredible. The district court apparently also accepted the defendants' position that such data were required to be included in the specification. However, the purported authority cited by the defendants concerned quite different issues, where, for various reasons, it was appropriate to offer experimental evidence. For example, the district court relied on patent "interference" cases, as in *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1324 (Fed. Cir. 2005), where evidence of actual reduction to practice was required to establish a priority date earlier than that of an adverse claimant.

When priority is not at issue, generally the applicant may provide data obtained either before or after the patent application was filed. With reference to demonstration of utility, in *Brana*, 51 F.3d at 1567 n.19 the court noted that post-filing evidence "can be used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification." Here, the utility of tomoxetine is accurately stated in the specification; there is no allegation of falsity in the disclosed utility, and the patent examiner did not require the presentation of additional data. In *In re Marzocchi*, 439 F.2d 220 (CCPA 1971) the court had explained that:

> The only relevant concern of the Patent Office under these circumstances should be over the truth of any such assertion. The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.

439 F.2d at 223. The '590 patent describes and enables the utility of tomoxetine to treat ADHD. The disclosure is not "on its face, contrary to generally accepted scientific principles." *Id.* at 223. Lilly's expert testified that the utility of tomoxetine to treat ADHD "had not been ruled out," Trial Tr. 1099:4, and even the defendants' expert testified that "it could work." Trial Tr. 200:22.

The defendants rely on *Janssen Pharmaceutica N.V. v. Teva Pharmaceuticals USA, Inc.*, 583 F.3d 1317 (Fed. Cir. 2009) where the court held that the use of galantamine to treat Alzheimer's disease was a "mere research proposal." The specification summarized six scientific articles on the properties of galantamine to raise blood levels of cortisol and ACTH, and reporting brain effects in mammals, and the court held that because the animal tests were "not finished . . . by the time the '318 patent was allowed," enablement was not shown. The court held that there was not "a reasonable correlation between a compound's activity and its asserted therapeutic use," in the words of MPEP §2107.03. In the case of atomoxetine, however, the norepinephrine relationship was known, safety for antidepressant activity had been established, the specification contained a full description of the utility, experimental verification had been obtained before the patent was granted, and the examiner had not requested additional information. There was no evidence that the disclosure is "on its face, contrary to generally accepted scientific principles." *Marzocchi*, 439 F.2d at 223.

As stated in *Brana*, 51 F.3d 1566-67: "Even if one skilled in the art would have reasonably questioned the asserted utility, i.e., even if the PTO met its initial burden thereby shifting the burden to the applicants to offer rebuttal evidence, applicants proffered sufficient evidence to convince one of skill in the art of the asserted utility."

On the entirety of the evidence, invalidity for lack of enablement/utility was not shown by clear and convincing evidence. The district court's holding of invalidity on this ground is reversed.

V

INFRINGEMENT

The district court held that the defendants would be liable for inducement to infringe the '590 patent by providing atomoxetine bearing the FDA-approved label authorizing use to treat ADHD. The defendants argue that "the mere distribution of generic atomoxetine products cannot establish inducement liability, even though the labeling includes the legally required statement of FDA-approved use." Lilly responds that the label use to treat ADHD is the only legally approved use, and the only use for which the defendants are authorized to provide the product.

The defendants rely on *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003), for its finding of noninfringement, although in that case the patent on the only FDA-authorized use had expired, and the court held that the provider of the generic product, labeled for the authorized use on which the patent had expired, did not infringe a different (unexpired) patent on an unauthorized use:

> [T]he request to make and sell a drug labeled with a permissible (non-infringing) use cannot reasonably be interpreted as an act of infringement (induced or otherwise) with respect to a patent on an unapproved use, as the ANDA does not induce anyone to perform the unapproved acts required to infringe.

316 F.3d at 1364-65.

The defendants also argue that there are off-label uses of atomoxetine, stated by the defendants to be as high as 29% of the total, and conceded by Lilly as possibly as high as 8% of the total. However, the product sold by the defendants is labeled solely for the patented use to treat ADHD. We have long held that the sale of a product specifically labeled for use in a patented method constitutes inducement to infringe that patent, and usually is also contributory infringement. *See Astrazeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) (finding intent to induce infringement based on the product label authorizing the patented use, which "would inevitably lead some consumers to practice the claimed method"); *see also DSU Med. Corp. v. JMS Co. Ltd.*, 471 F.3d 1293, 1305-06 (Fed. Cir. 2006) (en banc in relevant part) (finding liability for induced infringement when an entity "offers a product with the object of promoting its use to infringe, as shown by clear expression or other affirmative steps taken to foster infringement").

No clear error has been shown in the district court's findings and conclusion regarding inducement. We affirm the judgment that the provision of atomoxetine labeled solely for use to treat ADHD constitutes inducement to infringe the '590 patent.

As for contributory infringement, the district court held that liability is avoided if the product has any "frequent" non-infringing use. Lilly argues that atomoxetine is not a "staple article of commerce suitable for substantial non-infringing use," the words of 35 U.S.C. §271(c), for the only authorized use of atomoxetine is the patented use to treat ADHD. The defendants are restricted from selling a federally regulated drug for unapproved uses. *See* 21 C.F.R. §202.1(e)(4). The defendants respond that physicians may nonetheless prescribe atomoxetine for unauthorized use. Such unauthorized activity does not avoid infringement by a product that is authorized to be sold solely for the infringing use.

We conclude that the district court erred in its application of the law of contributory infringement. That aspect of the district court's decision is reversed.

SUMMARY

The judgment that the '590 patent claims are invalid for lack of "enablement/utility" is reversed. The district court's rulings of validity on other grounds, and the judgment of infringement, are affirmed. We remand for further proceedings.

AFFIRMED-IN-PART, REVERSED-IN-PART, and REMANDED