PRECEDENTIAL

Filed May 23, 2003

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 02-3647

SHIRE US INC.,

Appellant

v.

BARR LABORATORIES INC.

On Appeal from the United States District Court
for the District of New Jersey
(D.C. Civ. No. 02-02023)
Honorable Joel A. Pisano, District Judge

Argued April 8, 2003

BEFORE: ALITO, FUENTES, and GREENBERG,
Circuit Judges

(Filed: May 23, 2003)

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OPINION OF THE COURT

GREENBERG, *Circuit Judge*.

I. FACTUAL AND PROCEDURAL HISTORY

A. Factual History

This matter comes on before this court on appeal from an order entered August 27, 2002, denying appellant Shire U.S. Inc.'s ("Shire") application for a preliminary injunction in its case against Barr Laboratories, Inc. ("Barr") charging Barr with trade dress infringement and trade dress dilution under sections 43(a) and (c) of the Lanham Act, 15 U.S.C. §§ 1125(a) and (c), and state unfair competition laws with respect to Shire's rights in Adderall, an unpatented drug Shire manufactures and sells. Adderall is a central nervous system stimulant used in treating attention deficit hyperactivity disorder (ADHD) available only by prescription

and dispensed to patients in pharmacy vials labeled "prescription-only" as required by law. Adderall is composed of the mixed salts of a single-entity amphetamine and is a controlled substance. Shire first placed Adderall on the market in 1996 and since that time it has enjoyed substantial success so that by 2001 it had a 32% market share in the United States ADHD prescription market.[1]

Adderall originally came in two dosage strengths and colors, 10 mg. (blue, round) and 20 mg. (orange, round). The tablets are currently either blue or pale orange/peach and either round or oval. Color and size vary with the tablet's strength, seven of which currently are prescribed: 5 mg. (blue, round), 7.5 mg. (blue, oval), 10 mg. (blue, round), 12.5 mg. (orange/peach, round), 15 mg. (orange/peach, oval), 20 mg. (orange/peach, round), and 30 mg. (orange/peach, round). Adderall tablets are scored and stamped with the mark "AD" on one side and the dosage size, *e.g.*, "10" on the other.

Recently, Shire sought a trademark for the Adderall trade dress. Shire's trademark applications sought protection for the overall configuration of the round tablet shape and the colors blue and orange used in conjunction with the "AD" marking. The United States Patent and Trademark Office (USPTO) initially has refused to register Shire's configuration.[2]

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1. In addition to Adderall, Adderall XR, and Barr's generic amphetamine salts, other currently marketed products used in the treatment of ADHD include: Ritalin, Ritalin SR, Methylin (generic branded methylphenidate), generic methyphenidate, Dexedrine, Cylert, Provigil, and Concerta.

2. The USPTO refused to register Shire's configuration "because the proposed mark appears to be functional." JA 1517. The examining attorney reached that conclusion because "the proposed mark consists of a design feature of the identified goods which serves a utilitarian purpose, namely, to hold and/or contain pharmaceutical preparations used for the treatment of attention deficit disorder and hyperactivity." *Id.* The examining attorney's letter goes on to explain that a mark may be functional in two senses: de jure and de facto. If a mark is de jure functional it is unregisterable. If a mark is merely de facto functional it may be registerable if it is either inherently distinctive or has acquired distinctiveness. The examining attorney found that Shire's "proposed mark is not inherently distinctive," JA 1518, and thus determined that even if the proposed mark was de facto and not de jure functional it only would be registrable with a showing of acquired distinctiveness. It appears that Shire did not submit evidence of acquired distinctiveness.

Shire's product literature, promotional materials, and mailings, which its sales staff distributed to physicians, feature color pictures of the Adderall tablets and sometimes direct patients to examine the tablets to ensure that they have received exactly the drug prescribed. Shire does not advertise its products in general consumer publications, but pictures of Adderall tablets appear in the Physician's Desk Reference and in certain consumer books. While Shire continues to sell Adderall, it altered its marketing strategy for 2002 and discontinued promoting Adderall, promoting instead a patented, sustained-release version of the drug, Adderall XR.

Barr, a public company that develops and manufactures generic and proprietary pharmaceuticals, was the first manufacturer of a generic equivalent to Adderall. It began developing a generic amphetamine salt alternative in 1998 and started marketing it in February 2002 after submitting an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") and obtaining its approval. The FDA has approved Barr's generic amphetamine salts as safe and effective, and has classified Barr's product, which it manufactures in accordance with FDA regulations, as therapeutically equivalent to Adderall. Barr's product is the bioequivalent[3] of Adderall, for which it thus may be interchanged freely. According to Shire, however, the products contain different inactive ingredients, and, in particular, Barr's tablets contain saccharin, a once controversial ingredient the FDA only recently removed from its list of banned substances.

Barr manufactures its generic amphetamine salts in 5 mg. (blue, oval), 10 mg. (blue, oval), 20 mg. (orange/peach, oval), and 30 mg. (orange/peach, oval) tablets.[4] Barr's

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3. The FDA rates a generic product "AB" equivalent to its branded counterpart if a study is submitted demonstrating bioequivalence to the branded product. Barr's generic product has an AB equivalency rating from the FDA.

4. For Barr's product to be approved as a generic equivalent for Adderall, it was required to produce the same dosage strengths available for Adderall. Shire, however, launched its mid-range dosages (7.5 mg., 12.5 mg. and 15 mg.) after Barr filed its ANDA with the FDA. In an internal memorandum, Shire indicated that its motivation for introducing these new strengths was to "buy time" to protect market share because generic substitutes would not be available for all strengths, thereby minimizing competition from substitutes.

generic amphetamine salts are oval[5] and convex in shape. Both the size and the color of Barr's tablets are linked to dosage. The face of the tablets has a "b" mark or the trade name Barr, and contains a numerical product code. The district court, on the basis of its physical examination of the tablets and the record before it, determined that while Barr's tablets, like Shire's, are blue and peach/light orange and those colors are keyed to dosage amounts, their shape and markings are different and "[j]uxtaposed against one another, the products are similar though not identical." JA 25.

B. Procedural History

On April 30, 2002, Shire filed this action against Barr, alleging that Barr's sale of generic amphetamine salts copying Adderall's appearance constituted unfair competition and diluted Shire's rights under federal and state law.[6] On May 3, 2002, Shire filed a motion seeking a preliminary injunction precluding Barr's use of a tablet with an appearance similar to that associated with the appearance of Shire's Adderall tablets.

On June 3, 2002, after the parties had engaged in limited, agreed-upon discovery, the district court heard oral arguments on Shire's motion. In a comprehensive opinion dated August 26, 2002, the court denied Shire's motion on the grounds that Shire had not credibly carried its burden of establishing that the color and shape of Adderall is non-functional. Therefore the court concluded that Shire was not likely to succeed on the merits of its case. The court entered the order denying the motion for a preliminary injunction on August 27, 2002,[7] but subsequently altered

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5. Barr chose the oval shape for its generic tablets without knowing that Shire planned to use an oval configuration for two of its new "mid-range" dosages. Shire does not assert any trade dress claims with respect to these new dosages.

6. The district court had jurisdiction pursuant to 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331, 1338(a), and (b). We have jurisdiction under 28 U.S.C. § 1292(a)(1).

7. The district court also found that inasmuch as a trade dress dilution claim similarly requires a showing of non-functionality, Shire was unlikely to prevail on that claim. In addition, the district court denied as moot two motions by Barr to strike materials that Shire submitted in support of its motion for injunctive relief inasmuch as the court determined that Shire was not entitled to a preliminary injunction.

parts of its opinion by an amended opinion dated September 16, 2002, which corrected inaccuracies in certain terminology used in the original opinion.[8] Shire filed a timely appeal on September 16, 2002.

II. DISCUSSION

A. Standard of Review

We approach this case recognizing that when ruling on a motion for preliminary injunctive relief, a district court must be convinced that consideration of the four following factors favors the granting of preliminary relief: (1) the likelihood that the moving party will succeed on the merits; (2) the extent to which the moving party will suffer irreparable harm without injunctive relief; (3) the extent to which the nonmoving party will suffer irreparable harm if the injunction is issued; and (4) the public interest. *See Clean Ocean Action v. York*, 57 F.3d 328, 331 (3d Cir. 1995); *AT&T Co. v. Winback and Conserve Program, Inc.*, 42 F.3d 1421, 1427 (3d Cir. 1994). As we have indicated, the district court determined that Shire had failed to satisfy the first prong of the test for preliminary injunctive relief,

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8. Shire suggests that the district court's amended opinion was the product of an improper communication between the court and Barr's attorney. *See* br. of appellant at 5 ("The opinion was subsequently altered after a communication by Barr's attorney to the Court (which was not shared with Shire's counsel), and a new written opinion was issued dated September 16, 2002.") We, however, have compared the opinions and determined that the district court made only minor terminological changes in the amended opinion. *See* JA 21 and JA 6-7 ("sought a trademark application for the Adderall trade dress" changed from "applied for trademark protection regarding Adderall"), ("its trademark application seeks protection only for the product's colors and shapes when used together with the 'AD' marking" changed from "its patent application seeks protection only for the product's colors and shapes when used together with the 'AD' marking") and JA 24, n.4 and JA 10, n.3 ("its trademark applications" changed from "its patent applications"). The court added a new footnote at the outset of its amended opinion explaining why it issued the opinion. This addition had the effect of changing the number of the subsequent footnotes so that footnote 4 in the amended opinion corresponds to footnote 3 in the original opinion.

finding that Shire was unlikely to succeed on the merits of its trade dress claim because it failed to demonstrate that the product configuration of Adderall is non-functional, which is one of the factors Shire needed to prove in order to prevail in an action for trade dress infringement.[9]

On this appeal we recognize that "[t]he decision whether to enter a preliminary injunction is committed to the sound discretion of the trial court, and will be reversed 'only if the court abused its discretion, committed an obvious error in applying the law, or made a serious mistake in considering the proof.'" *Duraco Prods., Inc. v. Joy Plastic Enters.*, 40 F.3d 1431, 1438 (3d Cir. 1994) (quoting *Loretangeli v. Critelli*, 853 F.2d 186, 193 (3d Cir. 1988)). However, "[a]lthough terms of an injunction are normally reviewed for abuse of discretion, any determination that is a prerequisite to the issuance of an injunction . . . is reviewed according to the standard applicable to that particular determination." *John F. Harkins Co. v. Waldinger Corp.*, 796 F.2d 657, 658 (3d Cir. 1986); *see AT&T v. Winback and Conserve*, 42 F.3d at 1427. Thus, we review the district court's factual determinations for clear error but exercise plenary review with respect to its legal conclusions. *See A & H Sportswear, Inc. v. Victoria's Secret Stores, Inc.*, 237 F.3d 198, 210 (3d Cir. 2000). Under the clearly erroneous standard, "a finding of fact may be reversed on appeal only if it is completely devoid of a credible evidentiary basis or bears no rational relationship to the supporting data." *American Home Prods. Corp. v. Barr Labs., Inc.*, 834 F.2d 368, 370-71 (3d Cir. 1987).[10]

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9. The other factors relate to secondary meaning or acquired distinctiveness and likelihood of product confusion. *See TrafFix Devices, Inc. v. Marketing Displays, Inc.*, 532 U.S. 23, 28-29, 121 S.Ct. 1255, 1259-60 (2001).

10. Shire suggests, citing our opinion in *Scott Paper Co. v. Scott's Liquid Gold, Inc.*, 589 F.2d 1225, 1229 n.3 (3d Cir. 1978), that "[b]ecause there was no live testimony and this case involved only documentary evidence, this Court is in an equally good position as the District Court 'to evaluate the evidence and need not be constrained as in cases where the credibility of a witness may be in issue.'" Br. of appellant at 19-20. Barr correctly points out, however, that in 1985 Fed. R. Civ. P. 52(a) was amended to provide that the clearly erroneous standard applies to the district court's factual findings "whether based on oral or documentary evidence", *see American Home Prods.*, 834 F.2d at 370, and that we thus have noted specifically that the position previously taken in *Scott Paper Co.* "is no longer tenable." *Id.* at 370 n.2

B. Likelihood of Success on the Merits

The Lanham Act, 15 U.S.C. § 1125(a),[11] establishes a cause of action for trade dress infringement. "Trade dress" refers to the design or packaging of a product which serves to identify the product's source. *See TrafFix Devices, Inc. v. Marketing Displays, Inc.*, 532 U.S. 23, 28, 121 S.Ct. 1255, 1259 (2001). The purpose of trade dress protection, like trademark protection, is to "secure the owner of the [trade dress] the goodwill of his business and to protect the ability of consumers to distinguish among competing producers." *Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763, 774, 112 S.Ct. 2753, 2760 (1992) (citation omitted).

Trade dress protection, however, is not intended to create patent-like rights in innovative aspects of product design. *Eppendorf-Netheler-Hinz GmbH v. Ritter GmbH*, 289 F.3d 351, 355 (5th Cir. 2002). Thus, trade dress protection, unlike patent law which is not implicated here, does not foster innovation by preventing reverse engineering or copying of innovative product design features. *Id.* "Trade dress protection must subsist with the recognition that in many instances there is no prohibition against copying goods and products." *TrafFix*, 523 U.S. at 29, 121 S.Ct. at 1260. Therefore, trade dress protection extends only to incidental, arbitrary or ornamental product features which identify the product's source. *Eppendorf*, 289 F.3d at 355. To establish infringement of its unregistered trade dress a plaintiff must prove that (1) the allegedly infringing feature is non-functional, (2) the feature is inherently distinctive or

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11. Section 1125(a) provides in pertinent part:

> Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person . . . shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

has acquired secondary meaning, and (3) consumers are likely to confuse the source of the plaintiff's product with that of the defendant's product. *See Wal-Mart Stores, Inc. v. Samara Bros., Inc.*, 529 U.S. 205, 210-211, 120 S.Ct. 1339, 1343 (2000).

The functionality doctrine "accommodates the twin purposes behind the Lanham Act. It protects the manufacturer (and the consumer) from the copying of those features that signify a product's source (and quality) and encourages competition by preventing one manufacturer from acquiring a monopoly by attempting to trademark those features of a design essential to a successful product of that type." *Standard Terry Mills, Inc. v. Shen Mfg. Co.*, 803 F.2d 778, 780-81 (3d Cir. 1986). However, the definition of "functionality" has not enjoyed such clarity. *See* 1 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION, § 7:67 (4th ed. 2001) (discussing the "plethora of definitions" for functionality). In *TrafFix*, the Supreme Court set forth two tests for functionality. First, the Court recognized the "traditional" definition of functionality: "a product feature is functional, and cannot serve as a trademark, 'if it is essential to the use or purpose of the article or if it affects the cost or quality of the article.'" *TrafFix*, 532 U.S. at 32, 121 S. Ct. at 1261 (quoting *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 165, 115 S.Ct. 1300, 1304 (1995) (quoting *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 850, n.10, 102 S.Ct. 2182, 2187 n.10 (1982))). In addition to the traditional definition, *TrafFix* recognized a second test for functionality: "a functional feature is one the 'exclusive use of [which] would put competitors at a significant non-reputation-related disadvantage.'" *Id.* (quoting *Qualitex*, 514 U.S. at 165, 115 S.Ct. at 1304).

The district court, applying the "traditional" definition of functionality[12] found that "[i]n reviewing the proofs, the

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12. The Court of Appeals for the Fifth Circuit recently noted that "[i]n light of *TrafFix*, the primary test for determining whether a product feature is functional is whether the feature is essential to the use or purpose of the product or whether it affects the cost or quality of the product." *Eppendorf*, 289 F.3d at 356. This is the test that the district court applied in this case. *See* JA 23 ("Generally, a feature is functional, and thus unprotected as a trademark, if it is essential to the use or purpose of the article or if it affects the cost or quality of the article.") (internal quotation marks omitted).

Court is not persuaded that the color and shape of Shire's product is non-functional."[13] JA 24. Preliminarily the court noted that, contrary to Shire's contention, Barr did not adopt the "identical trade dress developed by Shire for its Adderall product." *Id*. After an examination of the actual tablets the court found that the products have different shapes and markings and therefore while the products are similar, they are not identical.

In addition, the district court found that "the record developed for purposes of this injunctive relief application fails to support the conclusion that Shire's alleged trade dress is non-functional" inasmuch as Shire "falls short on its burden to prove non-functionality because it has not credibly rebutted Barr's theory that the similar color-coding and shape of the products are particularly meaningful for ADHD patients and enhance efficacy." JA 25-26. In reaching its conclusion the district court quoted the declaration of Lawson F. Bernstein, M.D., the affidavit of Cheryl D. Blume, Ph.D., and the declaration of Gregory Drew.

Dr. Bernstein's declaration explains, *inter alia*, that because ADHD patients overuse visual cues, (1) when therapeutically equivalent ADHD products have similar visual recognition properties, adult ADHD patients will experience less confusion in correctly identifying the agent and/or its dosage strength; (2) given that almost all patients require some initial dosage titration and a subsequent substantial majority require intermittent dosage adjustment, the color coding of a particular preparation of mixed amphetamine salts tablets confers a substantial degree of clinical functionality for the patient in the titration/adjustment process; (3) many adult patients may take multiple daily dosages of different strength amphetamine salts tablets, also inferring the usefulness of similar color-coding.

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13. Shire has the burden of proving non-functionality for Congress amended the Lanham Act in 1999 to provide that "[i]n a civil action for trade dress infringement under this chapter for trade dress not registered on the principal register, the person who asserts trade dress protection has the burden of proving that the matter sought to be protected is not functional." 15 U.S.C. § 1125(a)(3).

The district court quoted Dr. Blume's affidavit explaining that a generic drug's similar appearance to the branded product "enhance[s] patient safety and compliance with the medically prescribed dosing regimen" and that safety and compliance "would be particularly important for ADHD drugs when non-medical intermediaries (such as school secretaries) dispense mid-day doses to children [treated for ADHD]." JA 27. Dr. Blume's affidavit explains that "[d]osage form similarities enhance patient acceptance" and points to generic formulations of other central nervous system drugs that are identical or mirror the brand drug in color. *Id*.

The district court also noted that, concurring with both Dr. Bernstein and Dr. Blume, the declaration of Gregory Drew, a registered pharmacist and Vice President of Pharmacy Health Services for Rite Aid Corporation, explains that Rite Aid prefers that "the generic tablet look as similar to the branded tablet as possible" so as to "increase[ ] patient acceptance and comfort," as well as compliance and that "all other things being equal, Rite Aid will choose to stock the generic product that most closely resembles the branded product." *Id*.

The district court found that "Barr has not copied features signifying the Adderall source" and that "the color and shape of Barr's product are directly linked to the drug's efficacy in ADHD patients." JA 28. The court concluded that "Shire has failed to prove the requisite non-functionality as an initial step to gaining the desired relief here." *Id*. The court's functionality conclusion is a factual finding, *see Ciba Geigy Corp. v. Bolar Pharm. Co., Inc.*, 747 F.2d 844, 850 (3d Cir. 1984), that "may be reversed on appeal only if it is completely devoid of a credible evidentiary basis or bears no rational relationship to the supporting data." *American Home Prods.*, 834 F. 2d at 370-71.

Shire's primary argument is that the district court "committed an obvious error by failing to apply Third Circuit precedent which is contrary to the district court's ruling." Br. of appellant at 21. But as Barr points out, most of opinions on which Shire relies were district court opinions from the early 1980s[14] which the court here was

14. As Barr notes, those cases were decided prior to: (1) the enactment in 1984 of the Hatch-Waxman amendments to the Food, Drug and

not bound to follow. Br. of appellee at 35. In addition, even when Shire's district court case law is considered for its persuasive value, it does not support its contention that the court committed reversible error as a court must decide each trademark case on its own facts, *Dresser Indus., Inc. v. Heraeus Engelhard Vacuum, Inc.*, 395 F.2d 457, 461 (3d Cir. 1968), and the cases on which Shire relies are distinguishable on their facts. Most significantly, though the cases involved prescription drugs, none involved controlled substances[15] and in all of the cases there was evidence of the passing off of the defendant's product by pharmacists, *see Boehringer Ingelheim G.m.b.H. v. Pharmadyne Labs.*, 532 F. Supp. 1040 (D.N.J. 1980); *Hoffman La Roche, Inc. v. Premo Pharm. Labs., Inc.*, 210 U.S.P.Q. 374 (D.N.J. 1980); *Biocraft Labs., Inc. v. Merck & Co.*, 532 F. Supp. 1068 (D.N.J. 1980); *American Home Prods. Corp. v. Chelsea Labs., Inc.*, 572 F. Supp. 278 (D.N.J. 1982), *aff'd*, 722 F. 2d 730 (3d Cir. 1983) (table), or of an intent to induce illegal substitution on the defendant's part. *See Ciba-Geigy Corp. v. Bolar Pharm. Co.*, 547 F. Supp. 1095 (D.N.J. 1982), *aff'd*, 719 F.2d 56 (3d Cir. 1983).[16] Shire also relies on our opinion in *SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3d Cir. 1980), but *SK&F* also is distinguishable on its facts as in *SK&F* we found evidence of actual passing off by

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Cosmetic Act, Pub. L. No. 98-417, § 101, 98 Stat. 1585, 21 U.S.C. § 355(j), which established a federal policy favoring the marketing of therapeutic equivalents of generic drugs, (2) the 1999 amendment to 15 U.S.C. § 1125(a)(3) which places the burden of proving non-functionality of unregistered trade dress on the plaintiff, and (3) the Supreme Court's decisions in *Wal-Mart* and *TrafFix*. *See* br. of appellee at 35.

15. Dr. Salah Ahmen, senior vice president for research and development at Barr, testified on a deposition that Barr wanted its "product to have similar color to Adderall to avoid patient confusion, to improve patient compliance. Especially for this control drug." JA 496.

16. In the *Ciba-Geigy* litigation after we affirmed the order of the district court granting a preliminary injunction, 719 F.2d 56, the parties by stipulation converted the proceedings on the preliminary injunction to a trial on the merits so that a permanent injunction was entered and on further appeal we affirmed again. *Ciba-Geigy*, 747 F.2d 844.

pharmacists. *Id.* at 1063. Shire does not make a comparable claim in this case.[17]

It is true that in *SK&F* and several of the other cases on which Shire relies, the defendant offered affidavits and declarations of pharmacists and physicians making claims relating to functionality similar to those Dr. Bernstein, Dr. Blume and Mr. Drew have made in this case and that the courts in those cases did not credit the evidence. For example, in *SK&F* Dr. Shafer, a physician, submitted an affidavit in which he supported the sale of similarly configured generic tablets as he believed this configuration would enable the patient to feel confident that there was no change in the chemistry of the medication and that patients might become uneasy, confused or react adversely if the generic medication looked different from the market innovator. *Id.* at 1060-61. But we explained that the district court nevertheless "apparently chose not to credit the assertion of the Shafer affidavit, crediting instead the affidavits of Drs. Meyerson and Tannenbaum that in their experience the appearance of a drug bears no established relationship to its therapeutic efficacy." *Id.* at 1061. *SK&F* does not dictate, however, that we overturn the district court's findings of fact in this case because, in contrast to

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17. In addition, as Barr points out, there were other significant differences between the facts in the cases Shire cites and those here. First, the generic drugs in some of the cases Shire cites were identical in shape, color, and size to the brand names drugs, whereas here the district court found that while the products in this case are similar, they are not identical. *See, e.g. Ciba-Geigy Corp.*, 747 F.2d at 849 ("[Defendant's] capsules are identical to [plaintiff's] APRESAZIDE capsules except that each is imprinted with the name of its respective manufacturer."); *American Home Prods. Corp.*, 572 F. Supp. at 280 ("[B]y copying every physical feature distinguishable by the human senses, such as size, shape and color, the defendants have made their product 'look like' plaintiff's though in fact they are different.") *Boehringer*, 532 F. Supp. at 1045 (finding that defendant's drug was identical to plaintiff's tablet in "size, shape, and color"). Second, Shire relies on cases involving inferior quality generic drugs that did not adhere to the strict FDA standards with which generic drugs now must comply. *See, e.g., SK&F*, 625 F.2d at 1061 n.4 (noting FDA recall of defendant's product); *Boehringer*, 532 F. Supp. at 1045 (noting "potential bioequivalence problems" of defendant's product).

the district court's conclusions in *SK&F*, the district court in this case did credit the assertions made by Drs. Bernstein and Blume and Mr. Drew that were comparable to those of Dr. Shafer. Just as in *SK&F* we deferred to the district court's findings of fact it is appropriate for us to do so in this case as well.[18] After all, it is inherent in the very nature of the deferential appellate review of findings of fact that a court of appeals can and, indeed, should, depending on the records before it, uphold arguably inconsistent outcomes.

We also point out that while Shire is correct that the district court did not discuss most of the case law on which it relies, it concedes that the court did not ignore all precedents in its favor. Thus, after quoting at length from Dr. Bernstein's declaration explaining that there is clinical functionality when a generic drug is physically similar to the branded version, testimony which the district court credited, the court cited our opinion in *Ciba-Geigy*, 747 F.3d at 850-51, contrasting it as a case "affirming finding of non-functionality where district court found no 'medical or business considerations' compelled the size and shape of a drug." JA 26.

While district courts in this circuit have rejected functionality arguments similar to those the court credited

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18. We have case law that is consistent with a determination that the color and shape of drug tablets can be functional. In *Smith, Kline & French Laboratories v. Clark & Clark*, 157 F.2d 725 (3d Cir. 1946), one of the earliest cases involving generic drug substitution, Smith, Kline & French (SK&F) sought an injunction against the manufacture and sale of Clark & Clark's patent-infringing amphetamine tablets under New Jersey unfair competition laws. *Id.* at 726. We observed that the infringing tablets closely resembled those produced by SK&F in shape, color and scoring and that the two tablets were distinguishable only upon close examination. *Id.* at 730. We, however, refused to uphold an injunction beyond the life of SK&F's patent, stating that the patent aside, SK&F "has no exclusive right to sell amphetamine sulphate and it may not preempt the market in the drug" and finding that the various features of the amphetamine tablets were functional. *Id.* at 730-31. Nevertheless we upheld the district court's findings of unfair trade practices as the evidence showed that Clark & Clark's salesmen encouraged palming off of Clark & Clark's product for that of SK&F. *Id.* at 731.

in this case, other district courts, such as that in *Ives Laboratories, Inc. v. Darby Drug Co.*, 488 F. Supp. 394 (E.D.N.Y. 1980),[19] have credited similar testimony bearing on functionality. In *Ives* the manufacturer of the prescription drug cyclandelate sought an injunction against manufacturers of generic cyclandelate claiming that the defendants' use of the same capsule colors was "a false designation of origin" or a "false description or representation" of defendants' product. *Id.* at 398. But the district court in *Ives* found that capsule colors were functional in several respects. "First, many elderly patients associate the appearance of their medication with its therapeutic effect . . . . Second, some patients co-mingle their drugs in a single container and then rely on the appearance of the drug to follow their doctors' instructions. . . . Third, to some limited extent color is also useful to doctors and hospital emergency rooms in identifying overdoses of drugs." *Id.* at 398-99.[20]

The Supreme Court noted the district court's finding of functionality in *Ives* in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844, 853, 102 S.Ct. 2182, 2188 (1982), after it granted certiorari and reversed the judgment of the court of appeals which had reversed the district court.[21]

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19. The court of appeals reversed in *Ives*, 638 F.2d 538 (2d Cir. 1981), but the Supreme Court in turn reversed the court of appeals in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844, 102 S.Ct. 2182 (1982). Then, on remand from the Supreme Court, the court of appeals affirmed the district court. *Ives Labs., Inc. v. Darby Drug Co., Inc.*, 697 F.2d 291 (2d Cir. 1982) (table).

20. The court also stated that a "different situation would be presented if wholesalers, pharmacies and hospitals insisted on purchasing generic cyclandelate in colors identical to those of Ives so that they could unlawfully pass off the generic product as that of Ives. But nothing in the record suggests such a motive. The fact is that, not surprisingly, the colors have come to represent to large numbers of those taking cyclandelate not its source but its ingredients and their effects. The colors are thus functional to the patients as well as to doctors and hospitals." *Ives*, 488 F. Supp. at 399. As in *Ives*, in this case, in contrast to the cases on which Shire relies there has not been an allegation of passing off.

21. *Inwood v. Ives*, 456 U.S. at 853, 102 S.Ct. at 2188 ("[T]he court found that the blue and blue-red colors were functional to patients as

In addition, citing its opinion in *Inwood v. Ives* in *Qualitex*, the Court commented on the functional nature of the color of medical pills stating:

> [T]his Court has written that competitors might be free to copy the color of a medical pill where the color serves to identify the kind of medicine (*e.g.*, a type of blood medicine) in addition to its source. See [*Inwood v. Ives*] at 853, 858, n.20, 102 S.Ct. at 2188, 2190 n.20 ('Some patients commingle medications in a container and rely on color to differentiate one from another'); see also J. Ginsberg, D. Goldberg and A. Greenbaum, Trademark and Unfair Competition Law 194-195 (1991) (noting that drug color cases 'have more to do with public health policy' regarding generic drug substitution 'than with trademark law').

Qualitex, 514 U.S. at 169, 115 S.Ct. at 1306.

Here the district court credited Barr's evidence that similarity in tablet appearance enhances patient safety by promoting psychological acceptance. We reiterate that we recognize that district courts in this circuit have rejected arguments of functionality similar to those credited by the trial court in *Ives* and by the district court in this case, and that we have affirmed several of those factual determinations as not clearly erroneous. But, as we have said, those cases are distinguishable on their facts. Moreover, we have the benefit of the Supreme Court's most

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well as to doctors and hospitals: many elderly patients associate color with therapeutic effect; some patients commingle medications in a container and rely on color to differentiate one from another; colors are of some, if limited, help in identifying drugs in emergency situations; and use of the same color for brand name drugs and their generic equivalents helps avoid confusion on the part of those responsible for dispensing drugs. In addition, because Ives had failed to show that the colors indicated the drug's origin, the court found that the colors had not acquired a secondary meaning."); *see also id.* at 862 n.3, 102 S.Ct. at 2192 n.3 (White, J., concurring) ("for the patient-user, of course, the constancy of color and shape may be a psychologically reassuring and therefore as medically beneficial as the drug itself") (quoting 3 R. Callmann, Unfair Competition, Trademarks and Monopolies § 82.1(m), pp. 217, 213 (Supp. 1981)).

recent trade dress decisions[22] which caution against the over-extension of trade dress protection. In this regard we point out that there is language in several of the Court's opinions supporting a conclusion that the district courts in *Ives* and in this case did not err in their functionality conclusions. Overall we are satisfied that the district court, after it determined that by being physically similar to Adderall Barr's generic amphetamine salts tablets materially benefitted the patient population, did not clearly err in finding that Shire had failed to show that its product configuration was non-functional. Consequently, Shire did not demonstrate its likelihood of success on the merits and the court appropriately denied it a preliminary injunction.

III. CONCLUSION

For the foregoing reasons the order of August 27, 2002, will be affirmed.

A True Copy:
Teste:

Clerk of the United States Court of Appeals
for the Third Circuit

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22. With respect to the case law on which the district court relied, Shire distinguishes the Supreme Court's decision in *TrafFix*, 532 U.S. 23, 121 S.Ct. 1255, and our decision in *Standard Terry Mills*, 803 F.2d 778, and suggests that *Qualitex* "effects no change in the law." Br. of appellant at 28-29. While it is correct that *TrafFix* considered the evidentiary significance of expired patents in establishing functionality, a process not involved in this case, the facts remains that *TrafFix* did not confine its discussion of trade dress to this circumstance. For example, in *TrafFix* the Supreme Court reminded that "[t]rade dress protection must subsist with the recognition that in many instances there is no prohibition against copying goods and products" and cautioned against "misuse or over extension of trade dress [protection]." *TrafFix*, 532 U.S. at 29, 121 S. Ct. at 1260. With respect to our decision in *Standard Terry Mills*, while that case did not involve prescription medication, the district court correctly relied on it as precedent relevant to the definition of functionality and the purpose of the functionality doctrine. *See* JA 23-24, JA 28.