No. 95-3743

Rhone-Poulenc Rorer Pharmaceuticals, Inc.,

Plaintiff - Appellant,

v.

Marion Merrell Dow, Inc.,

Defendant - Appellee.

Appeal from the United States District Court for the Western District of Missouri.

Submitted: April 10, 1996

Filed: August 22, 1996

Before MAGILL, Circuit Judge, HENLEY, Senior Circuit Judge, and LOKEN, Circuit Judge.

LOKEN, Circuit Judge.

This appeal challenges the district court's[1] disposition of false advertising claims by competing manufacturers of diltiazem, a "miracle drug" for the treatment of hypertension and angina. The governing law is the false advertising cause of action provided in § 43 of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B). The court found both parties guilty of false advertising. It awarded no damages to plaintiff Rhone-Poulenc Rorer Pharmaceuticals ("RPR") and ordered RPR to undertake corrective advertising to counter the effects of its Lanham Act violation. RPR appeals those rulings. We vacate as not sufficiently specific that portion of the decree requiring RPR to advise the marketplace of "the food effect" associated with its product. We otherwise affirm.

[1] The HONORABLE DEAN WHIPPLE, United States District Judge for the Western District of Missouri.

I. Background.

Defendant Marion Merrell Dow ("MMD") introduced the first diltiazem drug, Cardizem, in 1982. The FDA approved Cardizem for the treatment of angina; it was also widely prescribed to treat hypertension. In 1989, MMD introduced a sustained release Cardizem product that is taken twice per day. MMD then developed Cardizem CD, a sustained release drug that is taken only once per day. The FDA approved Cardizem CD for hypertension and for angina.

Diltiazem was a pioneer new drug, which means that the Cardizem products enjoyed a ten-year period of market exclusivity under the Hatch-Waxman amendments to the Food, Drug, and Cosmetics Act. See 21 U.S.C. § 355(j)(4)(D); Abbott Labs. v. Young, 920 F.2d 984 (D.C. Cir. 1990), cert. denied, 502 U.S. 819 (1991). Cardizem products were immensely successful, generating sales of $1.1 billion in 1992 alone. By the early 1990's, competing drug manufacturers were anxious to penetrate the diltiazem market with less costly alternatives.

RPR launched its diltiazem drug in June 1992. RPR's Dilacor XR, a once-per-day sustained release tablet, initially received FDA new drug approval for the treatment of hypertension but not angina. FDA approval as a new drug, which is more rigorous than approval as a generic substitute, allowed Dilacor XR to compete with Cardizem CD during the latter's period of market exclusivity. FDA classified Dilacor XR as a "BC" drug -- one that is not necessarily "bioequivalent"[2] -- rather than a bioequivalent "AB" drug.

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[2]FDA will classify drugs as "bioequivalent" when their rate and extent of absorption by the body make them interchangeable. Drugs are bioequivalent when they have "the same strength and similar bioavailability in the same dosage form." Bioavailability is "the degree to which a drug or other substance becomes available to the target tissue after administration." Dorland's Illustrated Medical Dictionary 206 (27th ed. 1988).

Pharmacists may freely substitute among AB drugs, but only a prescribing physician may substitute one BC drug for another.

Given this FDA classification, to significantly penetrate the diltiazem market RPR had to persuade physicians to prescribe its low-cost product, Dilacor XR, as a substitute for Cardizem CD. MMD of course wanted to persuade the same audience that this is an inappropriate substitution. With this issue as the battleground, the two companies launched advertising campaigns for the allegiance of doctors, pharmacists, and hospitals. Because these are sophisticated consumers, the battle was waged with technical advertisements in professional journals and with marketing presentations by each company's sales representatives. RPR sought to convince prescribing physicians that Dilacor XR is the "same as, only cheaper" than Cardizem CD. MMD's message was, in essence, "not same as," and maybe not cheaper.

The nature of the competing false advertising claims can be briefly summarized. MMD's defensive advertising began with literature telling its sales representatives that Dilacor XR might be only seventy-five percent as bioavailable as Cardizem CD. After agreeing to discontinue that unsubstantiated claim, MMD's next wave of promotional materials advised sales representatives, doctors, and pharmacists that studies showed Dilacor XR only fifty percent as bioavailable as Cardizem CD. In its third wave of advertising, MMD released a four-page brochure in April 1993 reporting the results of a comparative study conducted by an outside laboratory, the "6730 Study." The results, as reported by MMD: "Dilacor XR delivers 81% of a 180-mg dose relative to Cardizem CD" and "74% of a 540-mg dose." RPR sued, contending that these false comparative bioavailability claims violate the Lanham Act.

Throughout this period, RPR's advertising urged doctors and pharmacists to switch their patients from Cardizem products to the low-cost Dilacor XR. In its counterclaims, MMD attacked this

advertising as falsely telling medical professionals that Dilacor XR is freely substitutable for Cardizem products when in fact Dilacor XR is not FDA-approved for angina,[3] physicians should monitor patients who switch from Cardizem CD because Dilacor XR does not have "similar bioavailability," and the two drugs are absorbed differently when taken with a meal (the "food effect").

After a bench trial, the district court found that MMD's early literature claiming that Dilacor XR has only seventy-five percent or fifty percent bioavailability violated the Lanham Act. It enjoined MMD from making those claims. However, it found that MMD's advertising based upon the 6730 Study was not false, and it declined to award RPR money damages because RPR failed to prove damage resulting from MMD's earlier false advertising.

Turning to MMD's counterclaims, the district court found that RPR's advertising "contain[ed] a hidden message encouraging indiscriminate substitution" that is false in two respects -- Dilacor XR is not approved for treatment of angina, and Dilacor XR has a "food effect" that creates a risk of injury if physicians do not monitor patients who are switched to Dilacor XR. Based upon these violations, the court enjoined RPR to "take necessary steps" to advise sales representatives, physicians, pharmacists, and patients (1) of "the food effect associated with Dilacor XR," (2) that physicians should "carefully monitor and titrate" (adjust the dosages) when they switch patients from Cardizem CD to Dilacor XR, and (3) that "Dilacor XR is not approved to treat angina."

Following the district court's September 1994 decision, RPR filed a motion to correct the judgment, which the court denied. MMD moved to enforce the court's order, and the court granted that motion without further explanation of what compliance is required.

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[3]Doctors may prescribe an FDA-approved drug for non-approved uses, but the manufacturer may not promote non-approved uses.

RPR appeals. It argues that MMD was guilty of false advertising based on the 6730 Study, that the district court erred in denying RPR money damages, and that the court erred in ordering RPR to conduct corrective advertising disclosing that Dilacor XR is not approved to treat angina and has a "food effect."

II. MMD's Advertising.

MMD advertised Dilacor XR's lower bioavailability in order to persuade medical professionals that Dilacor XR is not a comparable substitute and to undercut Dilacor XR's price advantage. The trial evidence showed that MMD's first claim of seventy-five percent bioavailability was false because it had no substantiation. The second claim of fifty percent bioavailability was false because it was based upon an obvious misinterpretation of data from prior studies. But MMD's third claim of 74% to 81% bioavailability was based upon the specially commissioned 6730 Study. The bona fides of that Study became a principal subject of the trial.

The Lanham Act prohibits "commercial advertising or promotion [that] misrepresents the nature, characteristics, qualities, or geographic origin of [the advertiser's] or another person's goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1)(B). False advertising decisions in other circuits have consistently distinguished between two types of comparative advertising claims: "my product is better than yours," versus "*tests prove* that my product is better than yours." To successfully challenge the first type of claim, a Lanham Act plaintiff must prove that defendant's claim of superiority is false. But to successfully challenge the second type of claim, where defendant has hyped the claim of superiority by attributing it to the results of scientific testing, plaintiff must prove only "that the tests [relied upon] were not sufficiently reliable to permit one to conclude with reasonable certainty that they established the proposition for which they were cited." Castrol, Inc. v. Quaker State Corp., 977 F.2d 57, 62-63

(2d Cir. 1992), quoting Procter & Gamble Co. v Chesebrough-Pond's, Inc., 747 F.2d 114, 119 (2d Cir. 1984). Accord BASF Corp. v. Old World Trading Co., 41 F.3d 1081, 1089-91 (7th Cir. 1994); Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1138 (4th Cir. 1993), cert. denied, 114 S. Ct. 1307 (1994); McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co., 938 F.2d 1544, 1549 (2d Cir. 1991). The district court applied this standard for "tests prove" claims to MMD's advertising based upon the 6730 Study. Neither party challenges the standard, and we agree it is a correct application of Lanham Act § 43.

RPR concedes that the 6730 Study results support the claims MMD made in its advertising brochure. Thus, the issue before us is whether that advertising was false because the 6730 Study is not a sufficiently reliable basis for comparing the bioavailability of Dilacor XR and Cardizem CD. At trial, RPR presented expert testimony that the 6730 Study was flawed in design and execution, plus evidence that two RPR studies, the "113 Study" and the "115 Study," did not have these flaws and refuted the bioavailability conclusions of the 6730 Study. MMD countered with expert testimony supporting the 6730 Study's methodology and attacking the RPR studies. After weighing this conflicting evidence, the district court concluded that the 6730 Study is a valid study "conducted by standards accepted within the scientific community and consistent with FDA principles."

On appeal, RPR concedes that the district court was free to reject RPR's evidence attacking the 6730 Study's methodology. But RPR argues that the results of its two studies refuted the 6730 Study, thereby proving that MMD's study did not scientifically establish the inferior bioavailability of Dilacor XR. However, RPR's studies were not that conclusive. The single-dose 113 Study was more limited in scope and did not necessarily refute MMD's claims. The 115 Study was not available when MMD began advertising the results of the 6730 Study, was criticized extensively by MMD's

experts, and also showed a reduced bioavailability for Dilacor XR, albeit not as great as the difference found by the 6730 Study.

After carefully reviewing this evidence, we conclude the district court's finding that MMD did not falsely advertise the 6730 Study must be upheld. We do not have a "definite and firm conviction that a mistake has been made," the clear error standard in Anderson v. Bessemer City, 470 U.S. 564, 573 (1985). We note that Lanham Act liability for "tests prove" advertising requires proof that the tests are not "sufficiently reliable" to support the advertised conclusion with "reasonable certainty." To ensure vigorous competition and to protect legitimate commercial speech, courts applying this standard should give advertisers a fair amount of leeway, at least in the absence of a clear intent to deceive or substantial consumer confusion.

RPR also argues that it was entitled to money damages for MMD's earlier false advertising. The Lanham Act provides that a successful plaintiff "shall be entitled" to recover "any damages sustained." 15 U.S.C. § 1117(a). Plaintiff must prove both actual damages and a causal link between defendant's violation and those damages. See ALPO Petfoods, Inc. v. Ralston Purina Co., 913 F.2d 958, 968-69 (D.C. Cir. 1990). "[P]laintiff may not recover if he fails to prove that the defendant's actions caused the claimed harm." Harper House, Inc., v. Thomas Nelson, Inc., 889 F.2d 197, 209 (9th Cir. 1989), quoting Otis Clapp & Sons, Inc. v. Filmore Vitamin Co., 754 F.2d 738, 745 (7th Cir. 1985).

In this case, RPR did not attempt to prove that it incurred increased costs in countering MMD's false advertisements, one well-established method of proving Lanham Act damages. See ALPO, 913 F.2d at 969. Rather, RPR attempted to prove that MMD's false advertising resulted in $40 to $56 million of lost Dilacor XR sales. However, the district court found that Dilacor XR sales "exceeded [RPR's] initial predictions" and that "Dilacor XR is as

well-positioned as should be reasonably expected at this stage in its product history with or without [MMD's] anti-Dilacor campaigns." These findings are not clearly erroneous and are directly responsive to RPR's damage theory. Thus, the district court did not abuse its remedial discretion in declining to award RPR damages. See Abbott Labs. v. Mead Johnson & Co., 971 F.2d 6, 16-19 (7th Cir. 1992) (standard of review). Likewise, because MMD discontinued its earlier false advertising and did not violate the Lanham Act in advertising the 6730 Study results, the court did not abuse its discretion in declining to order MMD to conduct corrective advertising.

III. RPR's Advertising.

The district court found that RPR's advertisements conveyed a false hidden message encouraging indiscriminate substitution of Dilacor XR for Cardizem CD. It ordered RPR to engage in corrective advertising regarding the fact that Dilacor XR is not FDA-approved to treat angina, the need to monitor and titrate patients who switch from Cardizem CD to Dilacor XR, and Dilacor XR's food effect. RPR concedes that its advertisements encouraged physicians to consider the two drugs freely substitutable, and it does not appeal the order that it must effectively disclose the need to monitor and titrate patients who switch drugs. But RPR does contend that the district court erred in ordering corrective advertising disclosing that Dilacor XR is not approved to treat angina and has a "food effect."

A. Regarding the limited FDA approval issue, RPR notes that it has truthfully advertised Dilacor XR as approved for the treatment of hypertension. The district court erred, RPR argues, because a Lanham Act plaintiff alleging that advertising is false because it conveys a false *implicit* message must prove actual consumer confusion, and MMD presented no such proof. See Johnson & Johnson * Merck Consumer Pharm. Co. v. Smithkline Beecham Corp., 960 F.2d

294, 297-98 (2d Cir. 1992). We note that other Second Circuit cases have said that implicit falsity "should be tested by public reaction," not that a plaintiff such as MMD *must* prove confusion by consumer research. Coca-Cola Co. v. Tropicana Prods., Inc., 690 F.2d 312, 317 (2d Cir. 1982). But we need not resolve that issue because consumer confusion need not be proved if advertising is literally false.[4]

In assessing whether advertising is literally false, "a court must analyze the message conveyed in full context." Castrol, Inc. v. Pennzoil Co., 987 F.2d 939, 946 (3d Cir. 1993). Here, the record clearly supports the district court's finding that RPR's advertisements were literally false. The court focused on RPR advertisements featuring images such as two similar gasoline pumps or airline tickets with dramatically different prices, accompanied by the slogan, "Which one would you choose." The court found that these ads falsely represented that the two drugs may be indiscriminately substituted, in effect, a representation that Dilacor XR "has certain qualities that it in fact does not actually have." Abbot Labs., 971 F.2d at 14. Because the implicit message was literally false, the issue became one of remedy -- what corrective advertising would be appropriate. The district court determined that the false message would be remedied if RPR adequately explained the differences in the two products, including the fact that Dilacor XR is not approved to treat angina. There was no abuse of discretion in adopting that remedy. See First Bank v. First Bank Sys., Inc., 84 F.3d 1040, 1044 (8th Cir. 1996)

[4]Furthermore, MMD presented evidence of consumer confusion. One physician testified that an RPR representative told him that RPR's formulation of diltiazem "is the same as Cardizem CD." MMD produced affidavits from other physicians stating that they had been told by RPR representatives that the drugs are the same. MMD also produced RPR physician surveys suggesting that consumers viewed the two products as interchangeable. Cf. PPX Enters., Inc. v. Audiofidelity Enters., Inc., 818 F.2d 266, 271 (2d Cir. 1987).

(standard of review); Pfizer, Inc. v. Miles, Inc., 868 F. Supp. 437, 444 (D.Conn. 1994) (no false advertising when product differences are explained).

B. Turning to the food effect issue, we agree with RPR that one of the district court's critical findings is clearly erroneous. The evidence, particularly RPR's 113 Study, suggests that taking Dilacor XR with food will increase its overall extent of absorption by about nineteen percent, whereas taking Cardizem CD with food will decrease its overall extent of absorption by about thirteen percent. The district court translated that evidence into the following finding: "within an hour of taking [Dilacor XR] after eating a high fat meal, a patient will experience a release of between 19% to 33% of the 24 hour dose." But the evidence addressed the overall, twenty-four hour extent of absorption, not the amount of product released during the first hour. Based upon this misinterpretation of the evidence, the court accused RPR of "callous indifference toward the individuals ingesting its product" because "[a] patient with a weak heart who undergoes this quick release of up to 33% of the total daily dosage within an hour could experience serious health problems."

Although the court's finding of a quick release is not supported by the record, the evidence does support the general finding of a "food effect" because the bioavailability of Dilacor XR and Cardizem CD are more dissimilar if the products are taken during or after a meal. Indeed, FDA requires that RPR packaging caution consumers that Dilacor XR should be taken on an empty stomach. The issue then is how the district court's erroneous finding affects the validity of its order requiring RPR to advise physicians, pharmacists, and patients of Dilacor XR's food effect.

Rule 65(d) of the Federal Rules of Civil Procedure requires that "[e]very order granting an injunction . . . shall be specific in terms [and] shall describe in reasonable detail . . . the act or

acts sought to be restrained." The Rule "is designed to prevent uncertainty and confusion on the part of those to whom the injunction is directed, to avoid the possible founding of contempt citations on an order that is too vague to be understood, and to ascertain that the appellate court knows precisely what it is reviewing." Calvin Klein Cosmetics Corp. v. Parfums de Coeur, Ltd., 824 F.2d 665, 669 (8th Cir. 1987). Particularly in light of the erroneous finding regarding the nature of Dilacor XR's food effect, we conclude that this portion of the permanent injunction violates Rule 65(d) and must therefore be vacated. On remand, MMD may request additional injunctive relief regarding Dilacor XR's food effect, but it should advise the district court what specific corrective advertising disclosures are requested and why such injunctive relief is necessary over and above the disclosures imposed upon RPR by the FDA.

We vacate one portion of the district court decree: "that Rhone-Poulenc should take necessary steps to advise sales representatives, physicians, pharmacists and patients of . . . the food effect associated with Dilacor XR." In all other respects, the judgment of the district court is affirmed. RPR's motion to clarify the record on appeal is denied.

A true copy.

Attest:

CLERK, U. S. COURT OF APPEALS, EIGHTH CIRCUIT.