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IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION SEVEN

In re BAYCOL CASES I and II.

B204943

(Los Angeles County
Super. Ct. No. JCCP4217)

APPEAL from a judgment and an order of the Superior Court of Los Angeles County, Wendell R. Mortimer, Judge. Judgment affirmed in part and reversed in part with directions; appeal dismissed in part.

Green Welling, Jenelle Welling, Charles Marshall and Brian S. Umpierre for Plaintiff and Appellant.

Sidley Austin, Catherine Valerio Barrad, Steven A. Ellis and Brendan P. Sheehey for Defendant and Respondent.

INTRODUCTION

Plaintiff Douglas Shaw (Shaw) appeals from a judgment of dismissal entered after the trial court sustained the demurrer of defendant Bayer Corporation (Bayer) without leave to amend. Shaw also appeals from a subsequent order denying his motion for reconsideration. We dismiss the appeal as to the postjudgment order and as to the class action claims. We reverse the judgment as to Shaw's individual claims.

FACTUAL AND PROCEDURAL BACKGROUND¹

On June 26, 1997, the Food and Drug Administration (FDA) approved Bayer's application to market the drug Baycol in doses up to .3 milligrams in the United States. Bayer later obtained approval to market Baycol in dosages of .4 and .8 milligrams. Baycol, generically known as cerivastatin sodium, belongs to a class of cholesterol lowering drugs commonly referred to as statins. Statins work by blocking an enzyme involved in the synthesis of cholesterol. They are generally prescribed to people with high blood pressure and heart disease.

Bayer began marketing Baycol on February 18, 1998. At that time, cholesterol lowering drugs were among the fastest growing products in the pharmaceutical industry. Revenue from the sale of statins increased from \$2.9 billion in 1996 to \$9.5 billion in 2000. Estimated revenue from sales of statins for 2001 was in excess of \$14 billion, based on 70 million prescriptions.

Bayer marketed Baycol as an effective, "simple and safe" alternative to the other statins on the market. It claimed that Baycol had fewer and less severe side effects than

¹ On demurrer, the facts are those pleaded in the complaint and those of which judicial notice may be taken. (*Williams v. Housing Authority of Los Angeles* (2004) 121 Cal.App.4th 708, 719.)

other statins. It aggressively marketed Baycol to doctors as well as advertising Baycol directly to consumers.

Bayer obtained approval to market Baycol after clinical trials involving only 3,000 people. This was far fewer than the people involved in clinical trials of other statins. Additionally, early clinical trials indicated that Baycol was not more effective, and presented greater risks than other statins.

On August 8, 2001, Baycol lost its FDA approval and Bayer withdrew it from the market. Baycol users were advised to switch to another medication for lowering cholesterol.

The reason for the loss of FDA approval and the withdrawal of Baycol from the market was reports linking Baycol with rhabdomyolysis, an acute and sometimes fatal disease causing the destruction of skeletal muscle tissue. The disease causes a breach of the cellular membranes of the muscle tissue, releasing myoglobin and potassium into the bloodstream. This can lead to kidney failure and death, or to heart failure. The FDA received reports of 31 deaths in three years from rhabdomyolysis caused by the use of Baycol. FDA records showed 772 cases of rhabdomyolysis in people taking statins during the time Baycol was on the market; more than half of these cases were linked to Baycol.

Baycol also was linked to myositis and myopathy, diseases of the muscle tissue. Additionally, Baycol was less effective at lowering cholesterol than other statins.

Bayer knew as early as 1994 that Baycol lowered the ability of the liver to produce coenzyme Q10 (CoQ10). Risks of decreased CoQ10 levels include rhabdomyolysis, myositis, myopathy, congestive heart failure and other diseases.

Before Bayer began to market Baycol, SmithKline Beecham Corporation (SmithKline), Bayer's marketing partner, expressed concern over the risks associated with Baycol. SmithKline did not believe that Baycol was more effective than other statins, and was concerned over its dangerous side effects. The FDA also advised Bayer that Baycol was only minimally effective at lowering cholesterol as compared to other statins already on the market.

In 1998, Bayer placed a warning in the Physician's Desk Reference (PDR) that "[r]are cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with other [similar drugs]." Bayer later revised its PDR entry to state that rhabdomyolysis and other conditions had been reported since the introduction of Baycol, but "a causal relationship to the use of *Baycol* cannot be readily determined due to the spontaneous nature of reporting of medical events, and the lack of controls."

Bayer conducted additional studies to demonstrate the safety and efficacy of Baycol in conjunction with its attempt to obtain approval of higher doses of Baycol. These studies showed, however, that a higher dosage increased the risks of Baycol. Bayer did not disclose these increased risks.

In April 1999, the FDA reported that among the six statins on the market, incidents of rhabdomyolysis were highest for Baycol users. Other reports showed problems with Baycol as well. Bayer continued to characterize rhabdomyolysis as a rare side effect of Baycol, however. Bayer also advertised that Baycol provided "[t]he same proven safety and tolerability you've come to expect. Side effects are usually mild and transient and similar to a placebo."

On October 25, 1999, the FDA wrote to Bayer that it had "become aware of promotional material for *Baycol* . . . that is false, lacking in fair balance, and otherwise misleading." There was no substantial evidence that Baycol was "superior to competing products" or provided "a clinical advantage versus 'other statins.'" Additionally, the FDA stated, Bayer's "presentation of risk information . . . lack[ed] fair balance." The FDA directed Bayer to "immediately cease" its deceptive advertising.

Bayer continued to promote Baycol until August 8, 2001, when Bayer announced that it was withdrawing Baycol from the market for public safety reasons. It acknowledged that "rhabdomyolysis is a serious, potentially fatal effect of all statin drugs, including *Baycol*." At the same time, the FDA issued a notice linking Baycol to 31 deaths in the United States.

Following Bayer's withdrawal of Baycol from the market, thousands of plaintiffs filed suit against Bayer. (See *In re Baycol Products Litigation* (D. Minn. 2003) 218

F.R.D. 197, 201.) Shaw filed his action on September 5, 2001 in superior court in San Francisco County. He filed it as a class action alleging causes of action for unlawful, unfair or fraudulent business practices under Business and Professions Code section 17200 et seq. and for unjust enrichment. Shaw identified the class as “California residents who purchased or ingested the drug Baycol.” The basis of his action was Bayer’s false and misleading advertising regarding Baycol.

On Bayer’s motion, the action was removed to United States District Court of the Northern District of California. On October 26, 2001, Shaw moved to remand the action to state court.

Over a hundred federal cases against Bayer were coordinated in a multidistrict case in the District of Minnesota (*In re Baycol Products Liability Litigation* (MDL No. 1431)). Shaw’s case was one of those transferred, as of March 18, 2002.

A Plaintiffs’ Steering Committee was appointed by the court to represent all of the plaintiffs. (*In re Baycol Products Litigation, supra*, 218 F.R.D. at p. 201.) The committee filed a master class action complaint. It contained class action allegations on behalf of three separate classes: (1) the medical monitoring class, consisting of persons who took Baycol but had not yet manifested physical injury; (2) the personal injury class, consisting of persons who were physically injured as a result of taking Baycol; and (3) the refund class, consisting of persons who purchased Baycol for personal or family use. (*Id.* at p. 202.)

In the MDL, plaintiffs sought as to the refund class, which included Shaw, “restitution, disgorgement of profits and punitive damages based on claims of unjust enrichment and breach of implied warranty of merchantability” (*In re Baycol Products Litigation, supra*, 218 F.R.D. at p. 213.) The court concluded that the plaintiffs “failed to demonstrate that common issues of law predominate[d]” and therefore denied class certification. (*Id.* at pp. 214, 216.)

The decision in the federal action was filed on September 17, 2003. On February 11, 2004, Shaw moved for an order remanding his case to superior court in San Francisco. After initially denying the motion, on November 29, 2004, the federal court

granted Shaw's motion for remand. The court found it did not have subject matter jurisdiction over the case, in that Bayer had failed to establish that the amount in controversy for each class member exceeded the federal minimum.

Several hundred cases involving Baycol, including a number of class actions, which had been filed in California were consolidated in a Judicial Council Coordinated Proceeding (JCCP) in Los Angeles Superior Court. As in the MDL, a master complaint was filed in the JCCP. Shaw's case was added on to the JCCP on February 4, 2005.

During the next approximately two years, many of the cases in the JCCP were dismissed or resolved in Bayer's favor on summary judgment. On January 29, 2007, Shaw filed his first amended complaint, alleging causes of action for violation of the unfair competition law (UCL, Bus. & Prof. Code, § 17200 et seq.) and Consumers Legal Remedies Act (CLRA, Civ. Code, § 1750 et seq.), and for unjust enrichment.

Shaw sought to certify a class of "[a]ll persons who purchased or paid for the drug *Baycol* between February 18, 1998 and August 8, 2001 . . . , to be used by California Consumers, and not for resale." Excluded from the class were those who had been paid for personal injury related to Baycol use.

Shaw alleged that Bayer violated the UCL by engaging in unfair, unlawful and deceptive acts in marketing Baycol, and specifically that its acts violated the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), the Federal Trade Commission Act, section 5 (15 U.S.C. § 41 et seq.) and the CLRA. As a result of these acts, Bayer sold more Baycol at inflated prices than would otherwise have been the case. Shaw sought restitution and disgorgement of excess profits.

Shaw similarly alleged that Bayer violated the CLRA by falsely representing that Baycol was safe and effective. For this violation, he sought restitution and disgorgement of excess profits.

Shaw finally alleged that Bayer was unjustly enriched by revenues obtained due to its deceptive advertising. He sought imposition of a constructive trust for disgorgement and restitution of excess Baycol revenue.

On March 16, 2007, Bayer filed a demurrer to Shaw's first amended complaint. Bayer demurred to the class allegations "on the grounds that plaintiff is estopped from certifying a class, and there is no reasonable possibility of establishing a community of interest here." In particular, Bayer claimed that Shaw was estopped from relitigating the class certification issue that had been decided in the MDL. Bayer also claimed that class certification was inappropriate, in that individual issues predominated and plaintiff was not an adequate representative. Bayer additionally demurred to each cause of action on the ground it failed to state a claim. Shaw opposed the demurrer as to all causes of action except unjust enrichment, which he elected not to pursue.

The trial court sustained Bayer's demurrer without leave to amend on April 27, 2007. It explained: "This Class Action arises out of a federal MDL case in which the judge has already denied class certification. The Class Action is, therefore, barred by collateral estoppel and/or res judicata principals [*sic*]. That federal case involved this plaintiff and involved nationwide class allegations which necessarily included California. Even though the case now before this court involves a slightly different class definition and specifically pleads California statute (UCL & CLRA), the claims involve the same primary rights. . . ."

The trial court also sustained the demurrer without leave to amend "on a separate and distinct basis. Individual issues predominate. Each class member would need to show that Baycol provided no health benefits or that Baycol injured them. This would include each user's cholesterol levels before, during and after Baycol use. Individual issues would make a class action impracticable."

In addition, the trial court sustained the demurrer to Shaw's individual claims without leave to amend, stating: "Plaintiff did not plead that he did not receive health benefits, that he did not get what he paid for, or that he has any basis for injunctive relief. Plaintiff did not provide a prefiling notice as required by CC 1782."

On May 14, 2007, Shaw moved for reconsideration based on a change of law, citing the recent decision in *Fladeboe v. American Isuzu Motors Inc.* (2007) 150 Cal.App.4th 42. The trial court denied the motion on the grounds there were no new

facts or law justifying reconsideration. On October 24, 2007, the trial court entered a judgment of dismissal.

Bayer served notice of entry of judgment on October 29, 2007. Shaw filed his notice of appeal on December 20, 2007.

DISCUSSION

A. *Motion to Dismiss the Appeal*

1. **Timeliness**

Bayer contends the April 27, 2007 order sustaining its demurrer to Shaw's class claims was immediately appealable. Therefore, it further contends, Shaw's December 20, 2007 notice of appeal was untimely as to these claims, and the appeal must be dismissed as to them.

An order denying class certification is appealable. (*Linder v. Thrifty Oil Co.* (2000) 23 Cal.4th 429, 435.) However, an order sustaining a demurrer without leave to amend "is ordinarily not appealable, since the order is not a final judgment." (*Alch v. Superior Court* (2004) 122 Cal.App.4th 339, 359.)

An exception to the latter rule arises "in a class action if the legal effect of the order is 'tantamount to a dismissal of the action as to all members of the class other than plaintiff,' and if the order 'has virtually demolished the action as a class action.' [Citation.] California allows direct appeal of such a 'death-knell' order as a matter of state law policy." (*Alch v. Superior Court, supra*, 122 Cal.App.4th at pp. 359-360.) "Since, in theory, the individual plaintiff's action can go forward, the death knell doctrine fits comfortably into the exception to the 'one final judgment' rule that arises when parties have separate and distinct interests; when this is true, there can be a final and appealable judgment for each such party. [Citation.]" (*Farwell v. Sunset Mesa Property Owners Assn., Inc.* (2008) 163 Cal.App.4th 1545, 1547.)

An exception to the rule regarding the appealability of an order sustaining a demurrer without leave to amend has been applied where, as here, the trial court sustains

a demurrer without leave to amend as to both the class action allegations and the individual causes of action. (See, e.g., *Los Altos Golf & Country Club v. County of Santa Clara* (2008) 165 Cal.App.4th 198, 202.) We are reluctant to carve out exceptions to the rule and thus introduce an element of uncertainty into what has otherwise been the established rule. Would the exception apply only where, as here, a single order sustains the demurrer without leave to amend as to both the class and individual claims? Would it apply where separate orders address the class and individual claims? A bright-line rule would eliminate any uncertainty. Accordingly, we adhere to the rule that “in a class action if the legal effect of the order is ‘tantamount to a dismissal of the action as to all members of the class other than plaintiff,’ and if the order ‘has virtually demolished the action as a class action,’” the order is immediately appealable. (*Alch v. Superior Court*, *supra*, 122 Cal.App.4th at pp. 359-360.)

Since the April 27, 2007 order sustaining Bayer’s demurrer to Shaw’s class claims was immediately appealable, Shaw’s December 20, 2007 notice of appeal was untimely as to these claims. We therefore affirm the judgment dismissing the class claims.

2. Mootness

Bayer additionally contends that the appeal as to Shaw’s individual claims must be dismissed as moot. Bayer asserts that Shaw failed to raise any contentions regarding his individual claims in his opening brief, waiving any claim of error as to them. (*REO Broadcasting Consultants v. Martin* (1999) 69 Cal.App.4th 489, 500; *Badie v. Bank of America* (1998) 67 Cal.App.4th 779, 784-785.) Since Shaw has no individual claims, Bayer continues, he is not a member of the putative class (*Payne v. United California Bank* (1972) 23 Cal.App.3d 850, 859) and therefore has no standing to prosecute this appeal. We reject Bayer’s contention.

As Shaw points out, his argument in his opening brief addresses both his individual and his class claims. For example, Shaw refers to “the harm that Plaintiff alleges he suffered,” which “stems from being deprived of material information impacting his purchase decision.” Shaw argues that this harm differed from the harm at

issue in the federal MDL case. Thus, his argument addresses both individual and class claims.

B. *Standard of Review*

The court should not sustain a demurrer without leave to amend if the complaint, liberally construed, can state a cause of action under any theory or if there is a reasonable possibility the defect can be cured by amendment. (*Schifando v. City of Los Angeles* (2003) 31 Cal.4th 1074, 1081.) Plaintiff bears the burden of establishing that the trial court erred in sustaining the demurrer or abused its discretion in denying leave to amend. (*City of Atascadero v. Merrill Lynch, Pierce, Fenner & Smith, Inc.* (1998) 68 Cal.App.4th 445, 459; *Coutin v. Lucas* (1990) 220 Cal.App.3d 1016, 1020.)

On appeal from a judgment of dismissal after a demurrer is sustained without leave to amend, we assume the truth of the complaint's properly pleaded or implied factual allegations. (*Schifando v. City of Los Angeles, supra*, 31 Cal.4th at p. 1081.) We also consider matters which have been or may be judicially noticed. (*Ibid.*; *Sacramento Brewing Co. v. Desmond, Miller & Desmond* (1999) 75 Cal.App.4th 1082, 1085, fn. 3.) We review the trial court's ruling de novo, exercising our independent judgment as to whether a cause of action has been stated as a matter of law and applying the abuse of discretion standard in reviewing the trial court's denial of leave to amend. (*Montclair Parkowners Assn. v. City of Montclair* (1999) 76 Cal.App.4th 784, 790; *Hernandez v. City of Pomona* (1996) 49 Cal.App.4th 1492, 1497-1498.)

C. *Shaw's Individual Claims*

The UCL was enacted "to protect both consumers and competitors by promoting fair competition in commercial markets for goods and services. [Citation.]" (*Kasky v. Nike, Inc.* (2002) 27 Cal.4th 939, 949.) It "defines 'unfair competition' to mean and include 'any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by [the false advertising law ([Bus. & Prof. Code,] § 17500 et seq.).' ([*Id.*], § 17200.)" (*Kasky, supra*, at p. 949.)

A UCL action does not result in an award of damages to compensate a party for injury suffered. (*Bank of the West v. Superior Court* (1992) 2 Cal.4th 1254, 1268.) Rather, Business and Professions Code section 17203 provides that any person who has engaged in unfair competition may be enjoined and may be required “to restore to any person in interest any money or property,” i.e., to make restitution. (*Kraus v. Trinity Management Services, Inc.* (2000) 23 Cal.4th 116, 126.) The focus of the UCL is “on the defendant’s conduct, rather than the plaintiff’s damages, in service of the statute’s larger purpose of protecting the general public against unscrupulous business practices.” (*In re Tobacco II Cases* (2009) 46 Cal.4th 298, 312.)

The trial court sustained the demurrer as to Shaw’s individual claims on the ground that he “did not plead that he did not receive health benefits, that he did not get what he paid for, or that he has any basis for injunctive relief.” However, Shaw alleged that due to Bayer’s unfair, unlawful and deceptive acts in marketing Baycol, it sold more Baycol at inflated prices than would otherwise have been the case. At a minimum, it is reasonably probable that Shaw could amend his complaint to allege that due to Bayer’s unfair, unlawful and deceptive acts in marketing Baycol, *he* purchased Baycol and *he* purchased it at a higher price, than would have been the case had Bayer not engaged in unfair, unlawful and deceptive acts. Accordingly, he should have been given the opportunity to amend the complaint to provide more specificity as to his individual claims. (*Schifando v. City of Los Angeles, supra*, 31 Cal.4th at p. 1081; *City of Atascadero v. Merrill Lynch, Pierce, Fenner & Smith, Inc., supra*, 68 Cal.App.4th at p. 459.)

D. Other Issues

The other basis for sustaining the demurrer without leave to amend was Shaw’s failure to provide a prefiling notice as required by Civil Code section 1782. This section applies only to a CLRA claim. Shaw raises no contention, cites no authority and makes no argument as to the CLRA cause of action. Accordingly, he has waived any claim of error regarding the sustaining of the demurrer without leave to amend as to that cause of

action. (*Title G. & T. Co. v. Fraternal Finance Co.* (1934) 220 Cal. 362, 363; *Christoff v. Union Pacific Railroad Co.* (2005) 134 Cal.App.4th 118, 125.)

Shaw also raises no contention with respect to the order denying his motion for reconsideration. Again, this waives any claim of error as to the order. We therefore dismiss the appeal as to this order

DISPOSITION

The appeal is dismissed as to the class claims and as to the order denying reconsideration. The judgment of dismissal is reversed as to Shaw's individual claims only. The trial court is directed to vacate its order sustaining Bayer's demurrer without leave to amend as to Shaw's individual claims and to enter a new and different order sustaining the demurrer with leave to amend as to Shaw's UCL claim and without leave to amend as to his CLRA claim. The parties are to bear their own costs on appeal.

JACKSON, J.

We concur:

PERLUSS, P. J.

WOODS, J.