Legal Backgrounder

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DRUG PRICE REGULATION BY LAWSUIT HAZARDOUS TO AMERICANS' HEALTH

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The price of patented prescription medicines in the United States is at the center of a legal debate between several states and the federal government.[1] Helping fuel state initiatives to lower employee costs are studies that compare the price of particular prescription drugs in the U.S. to prices in Canada and other foreign countries.[2] Critics argue that U.S. consumers are subsidizing lower prices in the rest of the world.[3] Recently, plaintiffs' lawyers joined the fray on the side of the states, alleging a price fixing conspiracy by drug makers to keep prices higher in the U.S. than in their foreign markets. The case seems designed to incur negative publicity as a settlement tool and initiate broad discovery into the pricing records of major drugmakers.

On August 26, 2004, the law firm associated with the former mayor of San Francisco brought an action in California state court on behalf of a group of nineteen pharmacists against the world's largest pharmaceutical companies. The suit alleged that these companies conspired to fix the price of drugs in the U.S.[4] Plaintiffs stated that as a result of the anticompetitive conduct of the Defendants, pharmacists and their customers paid more for prescription drugs than they would have paid absent this alleged unlawful

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[1]Illinois recently announced that it would proceed with a plan to establish an online clearinghouse of state inspected pharmacies in foreign countries, including Canada, the United Kingdom and Ireland. Vermont has sued the Food and Drug Administration over its refusal to set up a prescription drug reimportation program. Additionally, California Governor Arnold Schwarzenegger recently vetoed several bills aimed at providing the citizens of California with access to drugs from Canada.

[2]U.S. House of Representatives, Committee on Government Reform and Oversight, Minority Staff Report, *Prescription Drug Pricing in the 1st Congressional District in Maine: An International Price Comparison.* Oct. 24, 1998.

[3]Patricia M. Danzon, *Making Sense of Drug Prices*, REGULATION Vol. 23, No. 1.

[4]*Tilley Apothecaries, Inc. v. Pfizer, Inc.,* No. RG604172428 (Cal. Super. Ct. filed Aug. 26, 2004). Pfizer, Inc., Johnson & Johnson, Inc., Merck & Co., Inc., Bristol-Myers Squibb Company, Abbott Laboratories, Wyeth, Eli Lilly & Company, GlaxoSmithKline, PLC, Allergan, Inc., Hoffmann-La Roche, Inc., Aventis Pharmaceuticals, Inc., AstraZeneca, Inc., Novartis Corporation, and Boehringer Ingelheim Corporation were all named as defendants in the lawsuit.

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conduct. This LEGAL BACKGROUNDER examines the various claims alleged by Plaintiffs in *Tilley Apothecaries, Inc. v. Pfizer, Inc.* (the "Complaint").

The Plaintiffs' Complaint contains a political diatribe concerning prescription drug sales and marketing practices. Plaintiffs contrast the notion of a profit-glutted pharmaceutical industry with the "elderly and disabled" who are forced "to pay exorbitant fixed and unlawful prices for drugs which the Defendants knew the elderly and disabled would have to pay because they are necessary for the maintenance of their quality of life." Complaint, ¶1. By invoking a stereotypical image of corporate greed versus the victimized elderly American consumer, the Complaint adopts rhetoric more appropriate for a political debate than a factual legal claim.

The central tenet of Plaintiffs' allegations is that pharmaceutical companies "formed a tacit trust and cartel, the purpose and effect of which is to collectively charge artificially higher prices for their drugs in the United States, including California, than they charge for the same drugs sold outside the United States, including Canada." *Id.* According to Plaintiffs, these companies maintained "unlawfully-fixed prices" in the U.S. by preventing the importation of lower-priced prescription drugs into the U.S. The suit also alleges that high prices were maintained by acts of "suppression" against the entry of generic drugs. Put simply, Plaintiffs contend that the reason that particular prescription drug prices are higher in the U.S. than in other countries is because the world's major pharmaceutical companies conspired to fix the price of virtually every prescription drug sold domestically.

The Complaint contains six causes of action. The first three claims allege that these companies violated the Cartwright Act (the California state equivalent of the federal antitrust laws) by agreeing to maintain artificially high prices of prescription drugs in the U.S. and conspiring together to take actions to maintain such prices by:

> restricting the importation of lower priced pharmaceuticals into the United States, including California; and taking collective actions to stop said importation, placing foreign wholesalers and retailers on artificial quotas to stop said customers from shipping into the United States, including California, refusing to sell to foreign wholesalers and retailers who ship pharmaceuticals into the United States, including California, and agreeing with wholesalers and retailers not to sell to persons who ship pharmaceuticals into the United States . . . Complaint, ¶¶ 50, 55, 60.

Plaintiffs offer no specific factual allegations supporting this alleged conspiracy. Nor do they offer specific factual allegations concerning how the Defendants implemented any of these alleged schemes to restrain competition.

Rather than offer specific facts to support these sweeping allegations of a grand conspiracy, Plaintiffs point to the fact that the pharmaceutical industry "ranks third in return on revenue with overall industry profit margins of 14%" and that the average drug price of the 38 drugs listed in the Complaint are higher in the U.S. than in Canada. Complaint, ¶¶ 46, 43. Notably absent from the Complaint is any reference to the price controls many countries, including Canada, place on drugs in their markets. The Cartwright Act, however, is very expansive in its application. Defendants may face a difficult task convincing a California state court judge to dismiss this case on the face of the complaint. While some federal courts have dismissed actions where a complaint relies entirely on legal conclusions and offers no factual support,[5] the burden on

[5]*See Oxford Asset Mgmt., Ltd. v. Jaharis*, 297 F.3d 1182, 1188 (11th Cir. 2002) (holding that a complaint must contain more than legal conclusions to survive a motion to dismiss); *Papason v. Allain*, 478 U.S. 265, 286 (1986) (holding that a court is "not bound to accept as true a legal conclusion couched as a factual allegation").

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Defendants in challenging the Complaint is a difficult one. As the California Supreme Court stated in *Quelimane Co., Inc. v. Stewart Title Guaranty Co.*:

[T]he rule established by *Chicago Title* essentially is that a plaintiff cannot merely restate the elements of a Cartwright Act violation. Rather, in order to sufficiently state a cause of action, the plaintiff must allege in its complaint certain facts in addition to the elements of the alleged unlawful act so that the defendant can understand the nature of the alleged wrong and discovery is not merely a blind 'fishing expedition' for some unknown wrongful acts.

As the court recognized in *Cellular Plus, Inc.* in the context of a price fixing agreement, "conspirators rarely make such agreements in the open or document their illicit agreements. Rather, it is usually the situation that such agreements are made covertly, thereby making it difficult for plaintiff to allege the full details of such . . . agreement prior to its ability to engage in the 'rock turning' allowed by discovery."[6]

Unfortunately, California courts require very little in the way of specific factual allegations in order for a plaintiff to meet this burden and survive a motion to dismiss. Even conclusory allegations of the type in Plaintiffs' Complaint are often sufficient. Ultimately, the question likely comes down to whether the trial court will allow Plaintiffs to engage in a "fishing expedition" using the discovery process to uncover *any* evidence to support claims brought pursuant to the Cartwright Act.

Plaintiffs, however, may have a difficult time meeting their evidentiary burden at the summary judgment stage. Upon a motion for summary judgment by Defendants, Plaintiffs must present *actual* evidence that, more likely than not, an unlawful conspiracy between the Defendants exits. *Aguilar v. Atlantic Richfield Co.*, 24 P.3d 493, 511-12 (Cal. 2001). Evidence of motive, opportunity, and means to enter into an unlawful conspiracy is insufficient because such evidence merely allows speculation about the existence of a conspiracy. *Id.* at 520. Speculation is not evidence. *Id.* Furthermore, "[a]mbiguous evidence or inferences showing or implying conduct that is as consistent with permissible competition by independent actors as with unlawful conspiracy by colluding ones" is not enough to survive a Defendant's motion for summary judgment. *Id.* at 511. Plaintiffs must present *actual* evidence that tends to exclude the possibility that the Defendants acted as independent market participants rather than co-conspirators. *Id.* Thus, the mere fact that prescription drugs are higher priced in the U.S. than in some foreign countries arguably should not meet Plaintiff's burden; rather, Plaintiffs will have to come forward with specific evidence showing that, more likely than not, Defendants conspired to fix the price of drugs in the U.S.

Plaintiffs' fourth claim alleges that Defendants' violated California's unfair competition laws by "charging prices in excess of those charged to Defendants' customers in other countries." Complaint, ¶ 64. Similar to the alleged violations of the Cartwright Act, Plaintiffs offer only conclusory allegations and fail to provide specific facts supporting those allegations. Pursuant to California's unfair competition laws, Plaintiffs seek restitution for the artificially high price of prescription drugs charged by Defendants, as well as injunctive relief to enjoin pharmaceutical companies from charging "discriminatory prices to Plaintiffs that are higher than the prices that are charged to foreign customers." Complaint, ¶ 65. Even assuming that Plaintiffs could ultimately present evidence that the alleged conspiracy did in fact exist, the question is not whether the price of particular prescription drugs in the U.S. is higher than the prices in Canada or some other foreign country. Rather, the ultimate question (and the measure of damages for Plaintiffs) is the difference between the price that the Defendants allegedly collectively agreed to sell prescription drugs in the U.S., and the price the Defendants could have charged independently in the U.S. absent the alleged conspiracy. The price of pharmaceuticals in Canada is of little relevance to the market price of

[6] *Quelimane Co., Inc. v. Stewart Title Guaranty Co.*, 960 P.2d 513, 525 (Cal. 1998) (quoting *Cellular Plus, Inc. v. Superior Court*, 14 Cal. App. 4th 1224 (Cal. Ct. App. 1993)).

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pharmaceuticals in the U.S. because many Canadian prices are established by a government commission based on the lowest prices charged in other countries set by the government, rather than the U.S. market. A similar law does not exist in the U.S.

Granting Plaintiffs' request for injunctive relief, which a court is unlikely to do, would prove disastrous and totally unworkable. Such a ruling, or related settlement, would require the judge to determine the "fair" price of prescription drugs and adopt a price point above which none of the Defendants could sell prescription drugs in California. Of course, different judges would pick different price points based on the individual facts and expert testimony of economists presented to the court. If similar actions ensued in other states based on favorable resolution of the California case, the result could be a patchwork of regulatory pricing schemes created by state court judges around the country. A question of such national importance as prescription drug price controls (and ultimately, that is what the Plaintiffs are requesting) should be left to Congress, which has previously and specifically rejected such an approach in favor of private pharmacy benefit management and volume purchasing pools.

The fifth claim alleges that Defendants violated California's unfair competition laws by conspiring to fix the price of prescription drugs at an artificially high level, and Defendants maintained such artificial prices by using "coercion and intimidation." Complaint, ¶ 71. Plaintiffs seek restitution of the "unfairly high prices" as well as injunctive relief pursuant to this cause of action. Plaintiffs, however, again offer no specific facts to support those sweeping allegations. The Complaint contains only the general allegation that "[i]n furtherance of the trust, and using the threat of termination and refusal to deal, Defendants have forbidden foreign subsidiaries, wholesalers and retailers from exporting Defendant-manufactured pharmaceuticals into the United States." Complaint, ¶ 45. This claim appears based on press accounts of company letters to Canadian suppliers, with no specific factual allegations regarding the coordination or communication between drug makers. Since it is ordinarily recognized that competition exists in most therapeutic drug classes, the independent actions of one or more drug makers, without specific evidence of communications between them, would be unlikely to support these specific claims. Plaintiffs will have to hope they can survive the court's initial evaluation of the Complaint's sufficiency under a likely motion to dismiss, with the primary goal of initiating a successful fishing trip through internal company documents that will either support their theories at trial or provoke settlement.

The sixth and final claim alleged in the Complaint is for violation of California's unfair competition laws as a result of Defendants' alleged violation of the Cartwright Act. Complaint, ¶ 78. Again, the Complaint repeats, in conclusory fashion, the same allegations contained in the previous claims.

The main thrust of this lawsuit is that, according to Plaintiffs, the pharmaceutical industry is *too* profitable and that this profitability is clearly the result of an unlawful conspiracy or other anticompetitive acts. The Complaint assumes that other companies fairly competing in the global economy do not have profit margins of 14%. Such a basis for launching this type of broad state antitrust claim is a thin reed, indeed. The lawsuit appears to have been filed first in the hope of eventually finding facts that may support Plaintiffs' theory. Whether or not a California judge permits Plaintiffs to engage in this type of "fishing expedition," the sad fact is that pharmaceutical companies will incur further negative publicity and large legal expenses to defend against conclusory and unsubstantiated allegations. Consequently, one of the ironies in this type of case is that the lawsuit will increase pharmaceutical companies' cost of doing business — which presumably will be costs which are passed along to purchasers in the form of higher prices. Absent some type of factual basis, these issues seem better suited for political debate and congressional review, rather than judicial oversight.

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