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*Analyzing the Laws, Regulations, and Policies
Affecting FDA-Regulated Products*

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On June 27, 2005, the California Court of Appeals for the Sixth Appellate District, comprising the county of Santa Clara in the Silicon Valley, held that a trial court cannot exercise personal jurisdiction over a defendant pharmaceutical company based “solely on the global exchange and management of medical and scientific information relative to drug safety and regulatory compliance.”¹ As a result of this holding, the foreign pharmaceutical companies in this case were dismissed as defendants from this action and could not be held liable to the plaintiffs, in the event of any verdict or settlement.

This decision has crucial and significant implications for international pharmaceutical companies with affiliates or related entities in California, and potentially other states that have yet to embrace this standard.

The facts underlying the appellate decision in *F. Hoffman-La Roche Ltd. et al.* involved a fourteen-year-old boy, Steven Wertheimer, who committed suicide subsequent to having been treated with Accutane[®], a prescription cystic acne medication. The deceased child’s parents, the Wertheimers, brought wrongful death and related product liability claims in the Santa Clara Superior Court against six affiliated “Roche” pharmaceutical companies, two of which are Swiss entities, F. Hoffman-La Roche Ltd. and Roche Holding Ltd. (collectively, the Swiss defendants), and two of which are American entities domiciled in New Jersey (the U.S. Roche entities). The U.S. Roche entities are wholly-owned subsidiaries of Roche Holding. Each of the Swiss defendants has a separate board and separate corporate assets from one another, and the U.S. Roche entities, respectively.

Swiss defendant F. Hoffman-La Roche Ltd. (F. Hoffman) is a Swiss corporation that manufactures and sells isotretinoin, the essential and active ingredient in Accutane[®], to its U.S. affiliates, while Swiss defendant Roche Holding Ltd. (Roche Holding) is a Swiss holding company that invests in pharmaceutical companies, including that of the U.S. Roche entities. Neither F. Hoffman nor Roche Holding manufactured, promoted, marketed, sold, or distributed Accutane[®] in California.

After having been served in Switzerland with the Wertheimers’ complaint from the Santa Clara Superior Court case, the Swiss defendants filed a motion to quash service of the summons on them, based on lack of personal jurisdiction. In California, a nonresident corporate defendant is not subject to a court’s jurisdiction or decisionmaking power, unless it has sufficient minimum contacts such that neither the California nor U.S. Constitutions’ notions of fair play and substantial justice are violated.² In other words, the nonresident defendant must have sufficient contact with California so that it reasonably can anticipate being subject to suit in the state.³ Such minimum contacts can give rise to

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¹ *F. Hoffman-La Roche, Ltd. et al., Petitioners v. The Superior Court of Santa Clara County*, 2005 Cal. App. Lexis 1018, at *2.

² *Pavlovich v. Superior Court*, 29 Cal. 4th 262, 268 (2002) (quoting *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)).

³ *Sonora Diamond Corp. v. Superior Court*, 83 Cal. App. 4th 523, 535 (2000) (citing *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980)).

either general or specific jurisdiction, terms of art further defined below, each of which is sufficient to subject the nonresident defendant to the power of the trial court.

For a court to exercise general jurisdiction over a foreign defendant, the latter must have substantial, continuous, and systematic contacts with California, even where the causes of action in the case are unrelated to the defendant's contacts.⁴ This typically requires that a foreign defendant have offices, bank accounts, or employees within the state or markets its products or services within the state. It was undisputed that none of these indicia existed with regard to the Swiss defendants.

Specific jurisdiction requires that the foreign defendant "purposefully avail" itself of California's benefits with respect to the actual matter in controversy; that the controversy is related to or arises out of the defendant's contacts with the forum; and that, as with general jurisdiction, exerting specific jurisdiction over the foreign defendant would comport with the applicable Constitutional principles.⁵ It was undisputed that the Swiss defendants had not purposefully availed themselves of any California benefits, given their lack of business presence in the state.

Due to the Swiss defendants' lack of any direct minimum contacts with the state of California, the Wertheimers could not rely on the typical bases for assertion of either general or specific jurisdiction and, instead, relied on a variation of general jurisdictional theory called "agency" or "representative services agency." To establish jurisdiction through agency, a parent or holding company must be shown to exercise such a degree of control over its California subsidiary company that the former can be said to manage and control the latter's day-to-day activities.⁶

The seminal case on the subject of jurisdiction arising out of parent-subsidiary relationships, *Sonora Diamond Corp. v. Superior Court*, holds that first, any such jurisdictional analysis should begin "with the firm proposition that neither ownership nor control of a subsidiary corporation by a foreign parent corporation, without more, subjects the parent to the jurisdiction of the state where the subsidiary does business."⁷ Indeed, the court held that there is only

one situation when the acts of the parent may be found to trespass the boundaries of legitimate ownership and control of the subsidiary and expose the parent to the power of the state in which the subsidiary does business ... [this situation arises where the parent] exercises such a degree of control over its subsidiary corporation that the subsidiary can legitimately be described as only a means through which the parent acts, or nothing more than an incorporated department of the parent.⁸

In order to establish an agency relationship between the Swiss defendants and the U.S. Roche entities, the Wertheimers had to make a strong showing "beyond simply facts evidencing 'the broad oversight typically indicated by [the] common ownership and common directorship' present in a normal parent-subsidiary relationship" and that the Swiss defendants had a "purposeful disregard of the subsidiary's independent corporate existence."⁹ The Wertheimers attempted to establish such agency between the Swiss defendants and the U.S. Roche entities, and the Santa Clara Superior trial

⁴ See, e.g., *Vons Companies, Inc. v. Seabest Foods, Inc.*, 14 Cal. 4th 434, 449 (1996).

⁵ *Sonora Diamond*, 83 Cal. App. 4th, at 536 (citing *Vons*, 14 Cal. 4th, at 446-47).

⁶ *Id.* at 541.

⁷ *Id.* at 540.

⁸ *Id.* at 541 (emphasis added).

⁹ *Id.* at 542.

court implicitly found that such agency did indeed exist, based solely on the Roche defendants' collaborative efforts concerning labeling of, and adverse drug events concerning, Accutane®.

As the court of appeals noted, while the Swiss defendants had no financial, manufacturing, distribution, marketing, or other day-to-day management control over either of the U.S. Roche entities, the Swiss defendants "managed the global collecting, study, or reporting of adverse drug events and corresponding labeling and regulatory issues" that culminated in a Core Data Sheet on Accutane®.

A Core Data Sheet is intended as a vehicle to help drug companies comply with the often-disparate adverse event reporting requirements imposed worldwide by providing a single document through which to measure the reportability of adverse drug experiences. The Food and Drug Administration (FDA), through its sponsorship of the International Conference on Harmonization (ICH)—a group composed of governmental and industry representatives charged with harmonizing international pharmaceutical regulatory requirements—encourages pharmaceutical companies to share labeling information among their international affiliates through such a Core Data Sheet.¹⁰ As summarized by FDA, the "only purpose of this document is to provide the company core safety information" for safety reporting to determine whether a particular adverse event is "listed" on the Core Data Sheet (which in turn determines the timing for regulatory reporting of the adverse event).¹¹ As a result, in compliance with various European regulatory bodies and as envisioned by FDA, F. Hoffman maintained a Core Data Sheet as a guideline of information to be included in an Accutane® products label.

While a Core Data Sheet may represent the unified scientific and medical opinion of a company (or group of affiliated companies) regarding a prescription drug—as mandated or encouraged by regulatory bodies around the world—a Core Data Sheet does not dictate or otherwise control the specific label in any particular country, including the United States, where the labeling of a prescription drug is expressly and extensively regulated by FDA. Therefore, while the evidence before the trial court did not support the notion that the Swiss defendants had control over the actual labeling of Accutane® in the United States, it established that the Swiss defendants were actively involved in compiling and maintaining the Core Data Sheet for compliance with various international regulatory requirements.

In rejecting, vacating, and overturning the trial court's order, the court of appeals specifically found that the "single sphere of global and collaborative Roche drug regulatory compliance and safety activities," in the form of the Core Data Sheet, is "alone . . . insufficient to establish general agency or control exerted over the U.S. Roche defendants by either Swiss Roche defendant." In other words, the Swiss defendants' activities concerning the Core Data Sheet were insufficient, under California's jurisdictional laws, to give rise to the valid exercise of jurisdiction over the Swiss defendants.

¹⁰ The full name of the ICH is the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, and its six co-sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health and Welfare; the Japanese Pharmaceutical Manufacturers Association; FDA; and the Pharmaceutical Research and Manufacturers of America. The Core Data Sheet was described in the ICH "E2C" standard. FDA then specifically promulgated a "guidance to industry" in 1997 to encourage pharmaceutical companies to comply with the ICH E2C standard. *See* ICH E2C: Clinical Safety Data Management: Periodic Safety Update Reports, 62 Fed. Reg. 27,470 (May 19, 1997). More recently, the FDA has proposed mandatory compliance with ICH E2C standards. *See* Safety Reporting Requirements for Human Drug and Biological Products, Proposed Rule, 68 Fed. Reg. 12,406 (Mar. 14, 2003).

¹¹ 68 Fed. Reg. at 12,422.

The court of appeals also took pains to distinguish the legal standards in a Florida case against the Swiss defendants that the trial court apparently had found persuasive on the issue of “control” between the Swiss and U.S. Roche defendants. In their arguments before the trial court, the Wertheimers relied in large part on an order from an Accutane[®] product liability case against the same Swiss defendants, venued in Florida federal court. In that case, *Bishop v. Hoffmann-La Roche Inc. et al.*,¹² the trial court found it could exercise personal jurisdiction over the Swiss defendants.

The California court of appeals explained that the *Bishop* decision was neither binding on or precedential for California courts. Further, the standards in *Bishop*, as contained in Florida’s jurisdictional statute, were very distinct from their counterparts in California and, therefore, according to the court of appeals, should not have been persuasive in this case.¹³ Florida’s jurisdictional statute specifically provides for jurisdiction based on agency.¹⁴ Moreover, the degree of control of the nonresident principal would have to be “very significant” under Florida law, rather than the “pervasive and continuous” higher burden mandated by California’s jurisdictional standards.¹⁵

With respect to F. Hoffman in particular, the court of appeals held that the company did not have the type of pervasive and operational control over either U.S. Roche defendant that would justify the exercise of personal jurisdiction over F. Hoffman. With respect to Roche Holding, the court of appeals held that “it is a true holding company, and there is nothing to suggest that the U.S. Roche defendants conduct their core pharmaceutical operations—manufacturing, distribution, sales, accounting, and finance—other than autonomously or that they do so simply in furtherance of Swiss Roche business.” *Sonora*, the governing case on the subject, holds that where a business of a foreign holding company is mere passive investment, the exercise of jurisdiction on a theory of agency is wholly improper.¹⁶

Most significantly, the court of appeals held:

A holding that jurisdiction over the Swiss defendants should be exercised solely due to their global, collaborative drug safety efforts would ultimately discourage such laudable and very topical efforts by pharmaceutical companies and lead to the *balkanization* of drug safety data, thereby reducing their completeness, accuracy, and consistency, and the speed and efficacy with which the data becomes available to drug regulators around the world. There are sound policy reasons for the encouragement, rather than penalization, of

¹² Case No. 8:02-cv-1533-T-30TBM (M.D. Fla., Tampa Div.)

¹³ According to the Florida statute:

(1) Any person, whether or not a citizen or resident of this state, who personally *or through an agent* does any of the acts enumerated in this subsection thereby submits himself or herself and, if he or she is a natural person, his or her personal representative to the jurisdiction of the courts of this state for any cause of action arising from the doing of any of the following acts:

(f) Causing injury to persons or property within this state arising out of an act or omission by the defendant outside this state, if, at or about the time of the injury, either:

1. The defendant was engaged in solicitation or service activities within this state; or
2. Products, materials, or things processed, serviced, or manufactured by the defendant *anywhere* were used or consumed within this state in the ordinary course of commerce, trade, or use.

FLA. STAT. § 48.193(1)(a), (f) (emphasis added).

¹⁴ See FLA. STAT. § 48.193, subd. (1).

¹⁵ *F. Hoffman-La Roche*, 2005 Cal. App. Lexis at *38.

¹⁶ *Sonora*, 83 Cal. App. 4th at 543.

worldwide, coordinated efforts by global drug companies to gather and report as much accurate information as possible concerning drug safety. *This activity alone* should not result in a court's exercise of jurisdiction over a foreign parent or affiliated pharmaceutical company, so long as the foreign company does not otherwise establish minimum contacts with California or purposefully avail itself of this forum, and the domestic pharmaceutical subsidiaries or affiliates, like the U.S. Roche defendants here, do not cede true operational control of their businesses to foreign parent or affiliated companies, thereby exposing them to the exercise of jurisdiction within the state.¹⁷

The lesson for all global pharmaceutical companies, and particularly those in California, is that there are strong public policy considerations that weigh against subjecting their foreign affiliates or parent companies to California courts, where the presence of such companies in the state is extremely limited. As embodied by the relationship between the various Roche entities, where a foreign affiliate's sole substantial contact with a forum and its domestic affiliates consists of centralizing, cooperating, exchanging, and collaborating with regard to drug labeling and adverse reporting information, there is no valid constitutional basis for the exercise of jurisdiction over the foreign entities in California. Given the decision discussed in *Bishop*, companies should nonetheless be aware of and sensitive to the jurisdictional standards of the venues in which their U.S. affiliates reside. Finally, global pharmaceutical companies should take pains to keep their operations, boards, finances, manufacturing and distribution channels, assets, and sources of direct income separate from their United States affiliates. Such companies, however, should not be afraid to share vital drug safety information mandated by regulatory bodies with their United States affiliates. This benefits the public greatly and does not deprive this self same public of an American defendant in the event a medication gives rise to legal claims.

¹⁷ *F. Hoffman-La Roche*, 2005 Cal. App. Lexis at *38 (emphasis added).