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***Recent Developments and Trends in
Personal Jurisdiction Over Foreign
Pharmaceutical Companies***

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I. INTRODUCTION

Courts within the United States have failed to develop clear standards for subjecting foreign manufacturers to jurisdiction in the United States for injuries caused by their products. Given the ease with which drugs can cross jurisdictional boundaries through new medium such as the internet, the lack of definite jurisdictional standards creates particularly troubling problems for pharmaceutical manufacturers. In view of the perils of jurisdictional uncertainty, this memorandum considers the standards governing personal jurisdiction over foreign pharmaceutical companies in the United States.

We provide an overview of the standards United States courts have developed for personal jurisdiction in the context of products liability cases, which are generally applicable to pharmaceutical cases. In addition, we analyze recent jurisdictional trends and developments related specifically to foreign pharmaceutical manufacturers. Our analysis includes a survey of recent decisions addressing jurisdiction over foreign pharmaceutical manufacturers; developments in jurisdictional jurisprudence as a result of the internet, including an analysis of jurisdictional issues raised by on-line pharmacies; and the implications for foreign pharmaceutical companies of changes in jurisdictional standards in mass tort cases.

In light of recent judicial trends, as analyzed herein, it is conceivable that in the future foreign pharmaceutical companies will be subject to jurisdiction in virtually every forum within the United States in which someone claims to have been harmed by their products. Indeed, pharmaceutical companies may even become subject to jurisdiction in forums in which they have no intention of selling or distributing their products.

II. THE BASICS OF PERSONAL JURISDICTION

Personal jurisdiction refers to a court's ability to exercise power over the parties and bind them by its adjudication. See Japan Gas Lighter Ass'n v. Ronson Corp., 257 F.Supp. 219, 224 (D.N.J. 1966). It is axiomatic that no party may be required to appear and defend a case in any court within the United States unless the court has personal jurisdiction over it.

The rules and standards governing personal jurisdiction arise from two sources. First, the “due process clause” of the Fourteenth Amendment to the United States Constitution, which forbids any state from “depriv[ing] any person of life, liberty or property without due process of law,” has been interpreted as limiting the places a person or entity can be required to defend a lawsuit. See Pennoyer v. Neff, 95 U.S. 714 (1877).

Second, individual states have enacted long-arm statutes or other rules which attempt to establish the boundaries of personal jurisdiction. See E. H. Schopler, Products Liability: In personam jurisdiction over nonresident manufacturers or seller under “long-arm” statutes, 19 A.L.R.3d 13 (2006). A significant portion of states have enacted statutes or rules which simply limit personal jurisdiction to the outer most bounds of the Fourteenth Amendment. Id. at § 22. In such states, the constitutional due process question and the question of statutory interpretation coincide. Other states have enacted statutes which expressly set forth specific standards for personal jurisdiction.¹ However, even where states purport to have their own jurisdictional standards,

¹ E.g. Verner v. Moran Towing & Transp. Co., 258 F.Supp. 169 (D.C.N.Y. 1966) (discussing New York long-arm statute which provides that personal jurisdiction may arise from “transacting business” in New York); Cecere v. Ohringer Home Furniture Co., 208 Pa. Super. 138 (1966) (discussing Pennsylvania long-arm statute which provides that personal jurisdiction may arise from “doing business” in Pennsylvania).

jurisdiction may never be stretched beyond what is permitted by the Fourteenth Amendment. See Asahi Metal Industry Co. v. Superior Court of California, 480 U.S. 102, 108 (1987).

As the Fourteenth Amendment defines the outer most limits of personal jurisdiction, this paper focuses primarily on the constitutional, rather than statutory, basis of personal jurisdiction. Indeed, the constitutional inquiry is significantly more important as a court will never have jurisdiction over a foreign person or entity unless the constitutional requirements are satisfied.

III. WHY DOES JURISDICTION MATTER?: A COMPARISON OF THE CANADIAN AND THE UNITED STATES JUDICIAL SYSTEMS

Significant financial implications will arise for a foreign pharmaceutical manufacturer subject to jurisdiction in the United States. The differences between the Canadian and United States judicial systems are demonstrative. Canadian litigants do not have a right to a trial by jury in civil cases and have fewer rights of appeal than do their American counterparts. See Richard Manning, Products Liability and Prescription Drug Prices in Canada and the United States, 40 J. Law & Econ. 203 (April 1997) Furthermore, punitive damages are much rarer in Canadian cases than in the United States, and the level of damages, both punitive and compensatory, are set by judges in Canada rather than juries. Id. Even if judges are not less willing to favor plaintiffs, Canadian judges often are limited by statute with regard to damage awards. Id. It has been suggested that the smaller damage awards typical of Canadian cases reflect fundamental societal differences between the two countries and, in particular, the existence of the broader social safety net in Canada. Id. Accordingly, if a

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pharmaceutical company is subject to jurisdiction in the United States, it likely faces greater exposure than it would in Canada or other jurisdictions.

IV. THE DEVELOPMENT OF PERSONAL JURISDICTION IN THE CONTEXT OF PRODUCT LIABILITY CASES

In broad terms, three concepts pervade the American discussion regarding personal jurisdiction. First, does the defendant have sufficient contacts, commonly known as “minimum contacts,” with the forum state to permit jurisdiction. See International Shoe Co. v. Washington, 326 U.S. 310 (1945). Second, has the defendant purposefully engaged in activity within the forum state. See Hanson v. Denckla, 357 U.S. 235 (1958). Third, does asserting jurisdiction over the defendant in the forum state offend traditional notions of fair play and substantial justice, *i.e.*, is it fair to require the defendant to defend himself in the forum state. See Asahi, 480 U.S. 102.

We begin our analysis by generally reviewing the historical development of the above concepts. Next, we examine how these concepts have been applied to product liability cases under a doctrine that has become known as the “stream of commerce theory.”

A. International Shoe And Its Progeny

1. The Emergence Of The “Minimum Contacts” Test

The personal jurisdiction doctrine has evolved from emphasizing a defendant’s physical presence in the forum state to also allowing constructive presence in the forum state. In 1877, the Supreme Court of the United States held that assertion of personal jurisdiction required the defendant’s physical presence within the physical territory of the forum state. Pennoyer, 95 U.S. 714. However, in 1945, in the landmark decision of

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International Shoe, the Supreme Court revised the personal jurisdiction requirements to include a "minimum contacts" alternative to physical presence in the forum state. 326 U.S. 310. The Court held that even though a defendant was not physically present within a forum state's jurisdiction, due process required only that the defendant "have certain minimum contacts with [the forum] such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." Id. at 319. The test of whether exercising jurisdiction would offend traditional notions of fair play and substantial justice has been recast by some courts as a reasonableness test, *i.e.*, given the level of contacts, is it reasonable to require the defendant to defend itself in the forum state. See World-Wide Volkswagen, 444 U.S. 286, 292 (1980). The nature and quantity of contacts required to satisfy the minimum contacts standard in the context of product liability cases is considered below.

2. Types Of Personal Jurisdiction: General And Specific Jurisdiction

There are two types of personal jurisdiction: "general" jurisdiction, which depends on a showing that the defendant has continuous and systematic contacts with the forum state sufficient to justify the state's exercise of judicial power with respect to any and all claims the plaintiff may have against the defendant; and "specific" jurisdiction, which exposes the defendant to suit in the forum state only on claims that "arise out of or relate to" a defendant's contacts with the forum. Helicopteros Nacionales de Colombia S.A., v. Hall, 466 U.S. 408, 414-15 (1984). The Supreme Court has not defined the exact amount of minimum contacts necessary to satisfy either of these tests. Rather, it has stated that this determination "cannot simply be mechanical or quantitative" and depends on the "quality and nature of the activity in relation to the fair and orderly administration

of the laws” which the due process clause was intended to insure. International Shoe, 326 U.S. at 319.

3. The Development Of The “Purposeful Availment” Requirement

The most difficult problem in applying the minimum contacts test has been defining the “quality and nature” that makes a contact sufficient to support jurisdiction. Many cases have relied on the statement in Hanson that the defendant must have “purposefully avail[ed] itself of the privilege of conducting business within the forum state, thus invoking the benefits and protections of its laws.” 357 U.S. at 253. This language emphasizes that the defendant must have made a deliberate choice to relate to the state in some meaningful way before it can be made to bear the burden of defending a case there. The Supreme Court has consistently held that the unilateral activities of the plaintiff or others will not do. E.g. World Wide Volkswagen, 444 U.S. at 292. The purposefulness requirement flows from the idea that when the defendant's interaction with the forum is intentional, it would be reasonable for the defendant to anticipate being haled into court there for any claims arising out of that interaction. Id.; Burger King Corp. v. Rudzewicz, 471 U.S. 462 (1985).

4. Comporting With Traditional Notions Of “Fair Play And Substantial Justice”

In Burger King, the Supreme Court held that once it has been decided that a defendant purposefully established minimum contacts within the forum state, these contacts may be considered in light of other factors to determine whether the assertion of personal jurisdiction would comport with traditional notions of “fair play and substantial justice.” 471 U.S. at 476. Thus, in appropriate cases, courts may evaluate “the burden on

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the defendant,” “the forum state's interest in adjudicating the dispute,” “the plaintiff's interest in obtaining convenient and effective relief,” “the interstate judicial system's interest in obtaining the most efficient resolution of controversies,” and the “shared interest of the several states in furthering fundamental substantive social policies.” Id. at 476-77 (citing World-Wide Volkswagen, 444 U.S. at 292).

These additional considerations identified in Burger King sometimes serve to establish the reasonableness of jurisdiction upon a lesser showing of minimum contacts than would otherwise be required. See e.g. Keeton v. Hustler Magazine, Inc., 465 U.S. 770, 780 (1984) (finding jurisdiction over magazine publisher where the burden of defending the case in the forum state was minimal); McGee v. International Life Insurance Co., 355 U.S. 220, 223-24 (1957). On the other hand, where a defendant purposefully directs his activities at forum residents, he must present a compelling case that the presence of some other considerations would render jurisdiction unreasonable. See Burger King, 471 U.S. at 477.

B. Personal Jurisdiction In Product Liability Cases: The Stream Of Commerce Theory

1. World-Wide Volkswagen: The Emergence Of The “Stream Of Commerce Theory”

In 1980, the Supreme Court adopted the stream of commerce theory in product liability cases to address jurisdictional issues arising from interstate and international commerce. See World Wide Volkswagen, 444 U.S. at 292. The stream of commerce theory was designed to confer jurisdiction in products liability cases in which the product has traveled through an extensive chain of distribution before reaching the ultimate

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consumer. Because a product manufacturer usually does not come into direct contact with a state when a product is marketed there by third parties, states needed a means to assert jurisdiction over a manufacturer when claims were filed regarding their products. World Wide Volkswagen, 444 U.S. at 293-94. As discussed below, the stream of commerce theory is essentially the application of general jurisdictional principles to the unique issues and problems raised in product liability cases.

For a forum state to exercise jurisdiction over a defendant through the stream of commerce theory, the defendant's contacts with the state must be such "that he should reasonably anticipate being haled into court there." Id. at 297. Jurisdiction over a non-resident manufacturer in a products liability suit is reasonable when the sale of the product in the forum state arises from the efforts of the manufacturer or distributor "to serve directly or indirectly, the market for its product" which has allegedly caused the injury at issue. Id. at 297. In other words, jurisdiction is reasonable as long as "a corporation delivers its products into the stream of commerce with the expectation that they will be purchased by consumers in the forum state." Id. at 298.

World-Wide Volkswagen involved a products liability suit by New York residents who were injured while traveling through Oklahoma.

The Court refused to allow jurisdiction to be based on one isolated occurrence in which the plaintiffs who bought an Audi in New York happened to be involved in an accident in Oklahoma. World-Wide Volkswagen, 444 U.S. at 295. Because an automobile is mobile by its design, it is foreseeable that an Audi sold in New York could cause injury in Oklahoma. Yet, foreseeability of the injury alone is not sufficient to establish personal jurisdiction. It must be foreseeable to the defendant based on its

conduct and connection with the forum State that it could be haled into court in the forum state. Id. at 297. Non-resident defendants should foresee being haled into court where the manufacturer or distributor spent effort to serve the forum state's market either directly or indirectly. Id. Therefore, a forum state may assert jurisdiction under the due process clause when an entity "delivers its products into the stream of commerce with the expectation that they will be purchased by consumers in the forum State." Id. The Court found a total absence of any circumstances indicating that the distributor and retailer defendants served the Oklahoma market or had any sufficient contact with the State and thus refused to allow the exercise of jurisdiction over the defendants.

2. Asahi Metals: Growing Uncertainty Over The Stream Of Commerce Theory

The Supreme Court again applied the stream of commerce theory to foreign defendants in Asahi Metal, 480 U.S. 102. In Asahi, the Court was confronted with the issue of "whether the mere awareness on the part of a foreign defendant that the components it manufactured, sold, and delivered outside the United States would reach the forum state in the stream of commerce constitutes 'minimum contacts' between the defendant and the forum state." Id. at 105. The Court concluded that jurisdiction was unfair under the reasonableness factors analysis. A majority of the court was not able to decide, though, how much contact is required by the defendant for the forum state to exercise jurisdiction under the stream of commerce theory.

The facts of Asahi helped the court to conclude that jurisdiction would be unreasonable because the only claim left involved two foreign parties. Asahi involved a products liability suit by a California citizen against a Taiwanese manufacturer of a motorcycle tire tube. While driving his motorcycle on an Interstate in California, Gary

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Zurcher lost control and collided with a tractor. He was severely injured and his passenger was killed. He alleged that his rear tire exploded after a sudden loss of air because the motorcycle tire, tube, and sealant were defective. Zurcher sued the Taiwanese manufacturer of the tube, Cheng Shin Rubber Industrial Co. The Taiwanese manufacturer filed a cross-complaint seeking indemnification from Asahi Metal Industry Co., the Japanese manufacturer of the tube's valve assembly. Cheng Shin settled all of its claims with Zurcher, leaving only the indemnification claim against Asahi. The Supreme Court ultimately refused to exercise personal jurisdiction over the indemnification claim.

The Court agreed that exercising personal jurisdiction over the defendant would be unfair under the "reasonableness factors" analysis, even though a majority of the Justices could not agree on whether a purposeful contact existed under the minimum contacts analysis. Asahi, 480 U.S. at 116. Under the reasonableness factors, the Court considered the "burden on the defendant, the interests of the forum State, and the plaintiff's interest in obtaining relief." Notably, the court held that the degree of the burden on the defendant is given significant weight when a foreign defendant is involved. The Court also considered that the procedural and substantive policies of Japan and Taiwan would be affected by California's assertion of jurisdiction over the alien defendant. Because the only claim left involved two foreign parties, the Court emphasized that a state should exercise great care when extending jurisdiction into the international field. Not only was the burden too high on Asahi, California's interest in the litigation was nonexistent, and the plaintiff did not demonstrate that it was more convenient to litigate the indemnification claim against Asahi in California rather than its foreign country.

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While the Court agreed that the exercise of jurisdiction violated due process based on the reasonableness factors, the Court did not obtain a majority view on the issue of purposeful contact. The Court issued three different opinions on whether the defendant had "purposefully availed" itself of the forum State to satisfy the minimum contacts test under the stream of commerce theory.

Justice O'Connor concluded that the mere placement of a product in the stream of commerce is not enough to establish a purposeful contact, and that a defendant must purposefully avail itself of the privilege of conducting activities in the forum states, or direct intentional acts towards the forum state to be subject to jurisdiction. . Asahi, 480 U.S. at 112. Justice O'Connor concluded that Asahi did not demonstrate any additional conduct purposefully directed towards California in order to justify asserting jurisdiction.

In a separate opinion, Justice Brennan, joined by Justice White, Justice Marshall, and Justice Blackmun, disagreed with Justice O'Connor's conclusion that Asahi did not "purposefully avail itself of the California market." Asahi, 480 U.S. at 116. Justice Brennan found that as long as the defendant was aware that the final product was being marketed in the forum state, the possibility of a lawsuit was foreseeable enough to make the exercise of jurisdiction reasonable. Even though Justice Brennan held that jurisdiction was unreasonable under the reasonableness factors analysis, he concluded that Asahi had established a purposeful contact under the stream of commerce theory.

Demonstrating the diversity of opinions in the case, Justice Stevens wrote a third opinion and argued that Justice O'Connor's opinion mistakenly assumes that an "unwavering line can be drawn between 'mere awareness' that a component will find its way into the forum state and 'purposeful availment' of the forum's market." Asahi, 480

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U.S. at 121. Justice Steven's opinion strongly suggested that an examination of minimum contacts was not even necessary since the court found that the exercise of jurisdiction would be unfair under the reasonableness factors analysis.

No opinion in Asahi commanded a majority regarding what level of contact is required by a defendant for the forum state to exercise jurisdiction under the stream of commerce theory. Therefore, the stream of commerce theory was not clarified by Asahi, but only further confused. The Supreme Court's decision in World-Wide Volkswagen that jurisdiction over the manufacturer must arise from the efforts of the manufacturer to serve the market either directly or indirectly still stands as the last decision commanding a majority of the Court on the level of contact needed to establish minimum contacts under the stream of commerce theory.

3. The Future Of The Stream Of Commerce Theory

Whether the Supreme Court will continue to follow Justice O'Connor's view of the stream of commerce theory or will adopt Justice Brennan's more expansive view cannot be known with any certainty. As discussed above, if Justice Brennan's approach is adopted, manufacturers could be sued in any jurisdiction where the stream of commerce could foreseeably sweep their products. In other words, mere awareness that a product could arrive in a foreign jurisdiction through the stream of commerce could be enough to establish personal jurisdiction. This is in stark contrast to the standard set forth by Justice O'Connor, which requires that the defendant must purposefully avail itself of the privilege of conducting activities in the forum states, or direct intentional acts towards the forum state to be subject to jurisdiction.

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Due to the state of the stream of commerce theory after Asahi, lower courts have been left to decipher which opinion appropriately addresses the level of conduct required to satisfy the minimum contacts standard in product liability cases. Instead of clarifying the issue, the way in which lower courts have responded to the Asahi decision has contributed to the uncertainty over the future of the stream of commerce theory. For example, federal appellate courts have adopted three different approaches to the stream of commerce theory in the wake of Asahi. The first approach has been an outright adoption of Justice O'Connor's standard as set forth in Asahi. E.g. Fortis Corp. Ins. v. Viken Ship Mang., 450 F.3d 214 (6th Cir. 2006) (setting forth standard for personal jurisdiction in Sixth Circuit). The second approach has been an adoption of Justice Brennan's opinion. E.g. Luv n' care, Ltd. v. Insta-Mix, Inc. 438 F.3d 465 (5th Cir. 2006) (holding that in the Fifth Circuit "mere foreseeability or awareness [is] a constitutionally sufficient basis for personal jurisdiction if the defendant's product made its way into the forum state while still in the stream of commerce"). Finally, other courts have simply declined to address the rift created by Asahi. E.g. Jennings v. AC Hydraulic A/S, 383 F.3d 546, (7th Cir. 2004). The courts that have found it unnecessary to resolve the differing Asahi opinions typically strive to resolve jurisdictional issues based on other criteria, such as whether jurisdiction would offend traditional notions of fair play. Id.

In all likelihood, the Supreme Court will issue another opinion on personal jurisdiction that will resolve the different standards applied by the lower courts. However, until the Supreme Court renders a definitive ruling, manufacturers, including manufactures of pharmaceuticals, should be aware that by merely placing a product into

the stream of commerce they *may* become subject to personal jurisdiction in every forum in the United States where their products could foreseeably arrive.

V. RECENT DECISIONS ADDRESSING PERSONAL JURISDICTION OVER FOREIGN PHARMACEUTICAL MANUFACTURERS

In this section of the paper we examine some of the more interesting cases that have addressed issues regarding jurisdiction over foreign pharmaceutical companies.

These cases are illustrative of a variety of jurisdictional issues that pharmaceutical companies may face.

A. Cases Analyzing Minimum Contacts And The Stream Of Commerce Theory As Applied To Pharmaceutical Companies

Set forth below are cases which have applied the stream of commerce theory or analyzed the minimum contacts standard. As discussed above, the future of the stream of commerce theory is uncertain and, therefore, any of these cases could be overturned. Subject to that caveat, these cases provide the best possible guidance to pharmaceutical companies with respect to jurisdictional issues. Indeed, these cases are illustrative of the various contacts that a foreign pharmaceutical company may have with a forum state, as well as whether such contacts will establish personal jurisdiction.

The most thorough analysis of the stream of commerce theory as applied to a pharmaceutical manufacturer is found in Tobin v. Astra Pharmaceutical Products, Inc., 993 F.2d 528 (6th Cir. 1993). In that case, the court held that it had personal jurisdiction over a Dutch drug manufacturer who marketed and sold its products through United States distributors. Of note, the Dutch manufacturer had submitted an application to the United States Food and Drug Administration for approval to sell the drug in the United

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States. Further, employees of the Dutch manufacturer conducted clinical studies in the United States for approval to sell the product here. Finally, the Dutch defendant expressly entered into an agreement with a distributor to sell the product throughout the United States.

The court purported to rely upon the plurality opinion in Asahi, and found that by “designing the product for the market in the forum state” it evidenced an intent or purpose to serve the forum state. In addition, the court held that the Dutch manufacturer’s direct efforts to obtain FDA approval allowed it to avail itself of the vast lucrative market in the United States.

In Tobin, there was more than just “mere awareness that the stream of commerce will sweep the product into the forum state.” Indeed, the facts evidenced the drug manufacturer’s deliberate decision to market the drug in all fifty states. Under these facts, the court found that the manufacturer could not reasonably expect the use of a distributor to insulate it from jurisdiction.

In contrast, the court in Fisher v. Professional Compounding Centers of America, Inc., 318 F. Supp. 2d 1046 (D. Nev. 2004), held that it did not have jurisdiction over an Italian drug manufacturer for injuries allegedly suffered as a result of a Nevada resident taking a diet drug in Nevada. The former subsidiary of the Italian company manufactured the diet drug’s active ingredient in Italy and distributed that ingredient to five United States companies, none of which were located in Nevada. Notably, the Italian company only distributed the ingredients for research and development, not for consumer use.

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In addition to the active ingredients in the diet drug at issue, the Italian company manufactured other pharmaceutical ingredients that regularly reached the United States market, including Nevada. These other active ingredients are sold to American manufacturer's who prepare final doses and distribute the product. None of the United States distributors used by the Italian company are located in Nevada. Furthermore, the Italian company owned no property in Nevada and had no employees, offices or bank accounts in Nevada. Under these facts, plaintiff argued that the Italian company was subject to general personal jurisdiction in Nevada. More specifically, plaintiff argued that by regularly placing products into the stream of commerce with knowledge that they would reach Nevada, the company had sufficient contacts to justify general jurisdiction, even though those specific products had no relation to the claim at issue in the suit in Nevada.

The court, without substantial analysis, found that there was not specific jurisdiction in this case because plaintiffs' alleged injuries did not arise from the manufacturer's contacts with Nevada. Accordingly, the court found that it lacked personal jurisdiction over the Italian company.

In Stetser v. TAP Pharmaceuticals Products Inc., 162 N.C. App. 518 (2004) and Commonwealth v. TAP Pharmaceuticals, 868 A.2d 624 (P.A. 2004), plaintiffs in North Carolina and Pennsylvania alleged that Takeda Chemical Industries ("Takeda") and other Japanese defendants engaged in fixing the price of medications. The facts and rulings of these cases are substantially similar and, therefore, are considered together. The facts of Stetser are set forth below. Both courts granted defendant Takeda's motion to dismiss for lack of personal jurisdiction.

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Takeda is a Japanese drug manufacturer. Plaintiffs alleged that Takeda and other defendants were involved in a conspiracy to defraud customers by fixing the price of medications. Takeda manufactured the drugs in Japan but did not design, manufacture, package, sell, ship or distribute the drug in the forum state. Under a license with Takeda, the drug was marketed by an Illinois company and sold in the United States by a subsidiary of TAP Pharmaceutical Products (“TAP”). Takeda owned fifty percent of TAP’s stock. TAP maintains its own headquarters, files its own taxes, holds regular board meetings, and hires its own employees. In other words, TAP runs its daily activities without instruction from Takeda.

Takeda was not licensed to do business in the forum state; it did not have a registered agent in the state; it did not own or lease land in the state; and it did not manufacture any products, sell any products, or earn any income from business in the forum state. In addition, Takeda did engage in the Japanese practice of “Secondment” with its foreign subsidiaries. “Secondment” is the practice of a parent corporation sending its employees to work at a subsidiary for a limited period of time. To that end, Takeda maintained a bank account in North Carolina in order to pay seconded employees.

Plaintiffs argued that Takeda was subject to jurisdiction in North Carolina because it conspired to carry out a fraud in that State. The court concluded that Takeda’s contacts, as described herein, were insufficient to support specific or general jurisdiction.

B. Cases Analyzing Jurisdiction Over Pharmaceutical Manufacturers Based On The Contacts Of Their Subsidiaries

Several recent cases have considered when, if ever, the contacts of a United States subsidiary can be attributed to a foreign pharmaceutical parent company for purposes of

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establishing minimum contacts. As discussed in the following cases, the more control and power a pharmaceutical company exercises over its subsidiaries, the greater the chance a United States court will attribute the contacts of the subsidiary to the parent.

For instance, in F. Hoffman-La Roche v. Superior Court, 130 Cal.App. 4th 782 (2005), the parents of a teenager who committed suicide brought a products liability action against multiple affiliated pharmaceutical companies, including two Swiss companies, alleging that a prescription drug's side effects caused the teenager's death. The Swiss companies argued that the California court did not have personal jurisdiction over them.

One of the Swiss companies, Roche Holding Ltd. ("Roche Holding"), is a joint-stock company with its registered office in Switzerland. The sole purpose of Roche Holding is to passively hold shares of companies that manufacture pharmaceuticals. Roche Holding was the parent corporation of the other Swiss defendant, F. Hoffman La Roche ("F. Hoffman"), as well as two New Jersey corporations. Plaintiffs conceded that Roche Holding did not have its own contacts with California. Instead, plaintiffs argued that Roche was subject to personal jurisdiction under an agency theory because it controlled corporations that were subject to jurisdiction in California. In support of that contention, plaintiff relied primarily on the fact that Roche Holding was involved in the global exchange and management of medical and scientific information relative to drug safety with the other companies.

While the court recognized that in some cases it may be appropriate to impose jurisdiction on a company based on the contacts of another company under an agency theory, the court found that there was no such agency relationship in this case. In

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accessing whether the subsidiary corporation was the agent of the parent corporation, the court considered how much control the parent exercised over the subsidiary. The greater the amount of control, the greater the probability the subsidiary will be deemed an agent of the parent.

The court squarely rejected plaintiffs' contention that Roche Holding controlled the companies simply based on the global collection of medical and scientific information. Accordingly, the Court found that the contacts of other companies could not be attributed to Roche Holding under agency principles and, therefore, held that the court lacked personal jurisdiction. Furthermore, the court found, as a matter of public policy, it would be unwise to impose jurisdiction in this case because doing so may discourage the exchange of vital drug information among related companies.

The other Swiss defendant, F. Hoffman, sold the active ingredient in the medication at issue to its U.S. affiliates. It was not disputed that F. Hoffman did not have direct contact with the California. Once again, plaintiffs argued that the court had personal jurisdiction over this defendant because it controlled companies that had contacts with California. The court likewise found that there was no jurisdiction over F. Hoffman because the record was devoid of facts establishing control sufficient to support an agency theory.²

In In re: Phenylpropanolamine (PPA) Products Liability Litigation, 344 F.Supp.2d 686 (W.D. Wash. 2003), the court held that the contacts of a United States subsidiary could be attributed to a foreign parent corporation for the purpose of establishing

² See also Snowden v. Connaught Laboratories, Inc., 793 F.Supp. 1040 (D. Kan. 1992) (holding that court lacked personal jurisdiction over parent company because it lacked control over wholly owned subsidiary); Hollander v. Sandoz Pharmaceuticals, 289 F.3d 1193 (10th Cir. 2002) (court lacked jurisdiction over Swiss parent corporation).

jurisdiction. In that case, a Swiss pharmaceutical company moved to dismiss a case filed in Oregon for lack of personal jurisdiction. Plaintiff argued that the court had jurisdiction over the Swiss company based on its relationship with its subsidiary. It was undisputed that the subsidiary had substantial contacts with Oregon.

The court began its analysis by finding that the mere presence of a parent-sub subsidiary relationship does not establish jurisdiction over the parent. Appropriate parent involvement that will not subject a parent to jurisdiction based on the subsidiary's contacts, includes: monitoring of the subsidiary's performance; supervision of the subsidiary's finances and capital budget decision; and articulation of general policies and procedures. In effect, the court determined that a parent corporation serving as a mere holding company cannot be subject to personal jurisdiction based on an agency theory.

In this case, the Court found that the parent corporation functioned as more than a holding company, and in fact, when the totality of the evidence was considered, the parent corporation actively controlled the subsidiary through its board, committees and executives. In addition, there were specific instances in which the subsidiary was required to get the approval of the parent (e.g., for the execution of supply agreements.). Accordingly, the court imposed liability on the parent corporation based on the contacts of its subsidiary under an agency theory.

C. Traditional Notions Of Fair Play And Substantial Justice As Applied to Pharmaceutical Companies

Whether imposing jurisdiction on a foreign pharmaceutical company would offend traditional notions of fair play and substantial justice hinges, as discussed above, on the facts of each case. That being said, the court's decision in Zeron v. Aventis, EP-04-CV-0141-FM (May, 2005), is instructive as to some of the factors courts will consider

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in deciding whether jurisdiction over a pharmaceutical company is fair. In Zeron, plaintiffs asserted various claims against two multinational pharmaceutical companies in state court in El Paso, Texas arising from the death of their son, following his use of a drug prescribed, purchased and administered in Mexico.

Both companies conceded that they had general contacts with Texas. The companies argued, however, that even though they had contacts with Texas, the court's assertion of jurisdiction over them in this matter offended "traditional notions of fair play and substantial justice." The court agreed with the defendants, and found that Texas lacked any compelling interest in the case, which arose in Mexico and would involve questions of Mexican law. Moreover, neither defendant could have reasonably anticipated being hauled into court in Texas to defend against claims involving this drug. For these reasons, the court found that personal jurisdiction would have violated traditional notions of fair play and substantial justice.

VI. THE WORLD WIDE WEB AND JURISDICTION: WHEN DOES A WEBSITE ESTABLISH MINIMUM CONTACTS ?

The development of the internet has given rise to new and unique jurisdictional issues. Indeed, pharmaceutical manufacturers should be mindful of the fact that their websites may create contacts with people around the world. The general principles set forth below should provide guidance to pharmaceutical companies with respect to the jurisdictional implications of websites. In addition, we analyze jurisdictional issues that may arise for drug manufacturers as a result of foreign on-line pharmacies selling their products to customers in the United States.

A. The Zippo Sliding Scale

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In Zippo Mfg. Co. v. Zippo Dot Com, Inc., 952 F.Supp. 1119 (W.D. Pa.1997), the court created the first and preeminent personal jurisdiction test tailored to the internet. In the most often-cited passage, the Zippo court stated that “the likelihood that personal jurisdiction can be constitutionally exercised is directly proportionate to the nature and quality of commercial activity that an entity conducts over the internet. This sliding scale is consistent with well-developed personal jurisdiction principles.” Id. at 1124. As a result, this internet-tailored personal jurisdiction test is known as the "Zippo sliding scale" and consists of three divisions.

At one end of the Zippo sliding scale, the defendant "clearly does business over the internet." The Zippo court cited activities such as entering into contracts with a resident of the forum state and repeatedly transmitting files over the internet to the forum state. Thus, a high level of commercial activity on a website correlates to a high likelihood that the court in the forum state can properly exercise personal jurisdiction.

At the other end of the scale, the defendant simply posts information on a website. Although the website may be accessible to internet users in the forum state, "a passive [website] that does little more than make information available to those who are interested in it is not grounds for the exercise [of] personal jurisdiction." According to the Zippo sliding scale, if a passive website has little commercial activity, there is a low likelihood that a court will assert personal jurisdiction.

Between the two ends of the sliding scale are "interactive" websites that allow users to exchange information with the website. The assertion of jurisdiction over interactive websites is "determined by examining the level of interactivity and commercial nature of the exchange of information that occurs on the [website]."

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However, the Zippo court did not provide further guidance for conducting this examination on interactive websites, such as how much interactivity or commercialism would suffice to assert personal jurisdiction or how interactivity and commercialism should relate to each other. Most courts facing the issue of exercising personal jurisdiction based on the defendant's internet activities have embraced the Zippo sliding scale.

Accordingly, if a pharmaceutical company's website passively conveys information, it is unlikely that the website will be relevant to a jurisdictional analysis. However, where a pharmaceutical company actively uses its website to promote its products and/or to target a specific jurisdiction, the company's website will likely be viewed as highly relevant for jurisdictional purposes. The ultimate importance of a pharmaceutical company's website will, of course, turn on the specific facts of each case.

B. On-line Pharmacies

Where a foreign on-line pharmacy sells and ships a product to someone within the United States, the online pharmacy will likely be subject to personal jurisdiction in the state where the product was shipped. In such a context, the on-line pharmacy has purposefully engaged in conduct directed toward the forum state for its own financial gain thereby establishing jurisdiction under World-Wide Volkswagen, 444 U.S. 286.

The more interesting question is whether a foreign drug manufacturer can be subject to jurisdiction in the United States as the result of a foreign on-line pharmacy shipping its product to the United States. Whether such a drug manufacturer could be subject to jurisdiction in the United States would likely turn on two issues already discussed in this memorandum. The first issue is whether the contacts of the on-line

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pharmacy can be attributed to the drug manufacturer. As set forth above, the contacts of a related entity are not attributable to a drug manufacturer unless the plaintiff can establish an agency relationship or that the related entity is the “alter-ego” of the drug company. Accordingly, in most cases, the pharmaceutical manufacturer will not be subject to jurisdiction based on the contacts of independent on-line pharmacies.

The second issue is whether a foreign drug manufacturer can be subject to jurisdiction in the United States as the result of a foreign on-line pharmacy shipping its product to the United States based on the stream of commerce theory. Whether a pharmaceutical company would be subject to jurisdiction in the United States in such a case would likely turn on which version of the stream of commerce theory is applied. Under Justice O’Connor’s approach, as set forth in the plurality opinion in Asahi, one must examine whether there is evidence that the drug company purposefully availed itself of the privilege of conducting activities in the forum state, or directed intentional acts towards the forum state. Asahi, 480 U.S. at 116; see also World-Wide Volkswagen, 444 U.S. at 295 (holding a state may assert jurisdiction where an entity “delivers its products into the stream of commerce with the expectation that they will be purchased in the forum state.”) In other words, the mere act of placing the product into the stream of commerce via an online pharmacy, without more, would be insufficient to establish personal jurisdiction over the drug manufacturer.

By contrast, if Justice Brennan’s approach in Asahi is applied, the mere fact that the drug was placed into the stream of commerce would be sufficient to establish jurisdiction if it was foreseeable that it could be purchased in the forum state. In view of these different standards, and the possibility that the standard could change,

pharmaceutical companies should be mindful that they *may* be subject to jurisdiction in any forum where an on-line pharmacy could foreseeably ship their products.

VII. A BRIEF NOTE ON PERSONAL JURISDICTION IN THE CONTEXT OF MASS TORTS: BEYOND INTERNATIONAL SHOE AND ITS PROGENY

In a limited number of reported decisions involving mass toxic torts, the minimum contacts standard, as it has developed since International Shoe, has been rejected. In general terms, mass tort cases are defined as cases involving the claims of numerous plaintiffs against a defendant for injuries caused as a result of that defendant's alleged tortuous conduct. Notably, pharmaceutical companies are often named as defendants in mass tort cases because multiple plaintiffs allege harm from their products.

The first reported case to reject traditional minimum contacts was Ashley v. Abbott Laboratories, 789 F.Supp. 552 (E.D.N.Y. 1992). Ashley was a mass tort case in which plaintiffs alleged that they were injured by a DES drug manufactured by the defendant pharmaceutical company. In that case, the court exercised jurisdiction over parties who had no minimum contacts, at least in the traditional sense, with the forum state, New York. The defendants expressly denied any pertinent activity in New York. Nevertheless, the court found a basis to proceed. It reasoned that:

“by competing to establish a territorial niche within the national DES market, every manufacturer directly or indirectly benefited from the Commerce Clause to the federal Constitution and the laws of every state in the nation by participating in the national market for the generic good... the United States constitutes a common economic pond that knows no state boundaries. A substantial interjection of products at any point of the national market has ripple effects in all parts of the market.”

[789 F.Supp. at p. 576; see also Hamilton v. Accu-Tek, 32 F. Supp. 3d 47 (E.D.N.Y. 1998) (court applies same “common economic pond” theory)]

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The holding of Ashley has been widely criticized and limited to mass tort cases. See Boaz v. Boyle & Company, Inc., 40 Cal. App. 4th 700 (rejecting the approach adopted in Ashley in lieu of a more traditional minimum contacts standard); see also Robert Tretter, Stop Fishing in the Pond and Get Back to the Stream: Personal Jurisdiction in Mass Toxic Torts, 1995 Ann. Surv. Am. L. 603 (1996). The fate of the ripple effects tests set forth in Ashley is, at best, uncertain.

Under Ashley, a foreign pharmaceutical company that sells drugs in limited parts of the United States may be subject to jurisdiction in states where it has no contacts on the theory that by participating in a segment of the United States market it has caused “ripple effects” in all parts of the country. However, there is *absolutely no* precedent that would support using the ripple effects theory to justify imposing jurisdiction on a foreign manufacturer that otherwise does not have sufficient contacts with any forum within the United States. For instance, jurisdiction over a Canadian pharmaceutical company may not be established by simply showing that the effects from its conduct in Canada ripple into the United States. Accordingly, the ripple effects test may be important for determining which courts within the United States have jurisdiction over a foreign pharmaceutical company where the company has minimum contacts with at least one forum within the United States, but should not serve to create jurisdiction in any court within the United States where the company’s contacts are otherwise insufficient to establish jurisdiction in the United States.

VIII. CONCLUSION

Under the approach adopted by some courts within the United States, a foreign pharmaceutical manufacturer is potentially subject to jurisdiction in every state in which

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the stream of commerce could foreseeably sweep its products. With the rise of the internet and on-line pharmacies, it is arguably foreseeable that drugs can be delivered almost anywhere within the United States. Accordingly, it is conceivable that in the future pharmaceutical companies will be subject to jurisdiction in virtually every forum in which someone claims to have been harmed by their product, even where a pharmaceutical company has no other contacts with the forum. Whether such an approach will be universally adopted by all courts is simply unknown. In view of this uncertainty, a prudent pharmaceutical company should be aware that it *may* be subject to personal jurisdiction in virtually every forum within the United States where someone claims to have been injured by its product.