

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,)
)
 Plaintiff,)
)
 vs.)
)
 F. HOFFMANN-LA ROCHE LTD,)
 ROCHE DIAGNOSTICS GMBH,)
 AND HOFFMANN-LA ROCHE INC.,)
)
 Defendants)

CIVIL ACTION No.: 05-CV-12237WGY

**DEFENDANT F. HOFFMANN-LA ROCHE LTD.'S REPLY MEMORANDUM IN
FURTHER SUPPORT OF ITS MOTION TO DISMISS**

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I. PRELIMINARY STATEMENT

Amgen fails to meet its burden of demonstrating a *prima facie* case of personal jurisdiction over Roche Switzerland, and instead relies upon inexact generalizations and theories. Amgen again blurs its terms, sometimes using “Defendants”, sometimes using “foreign Roche defendants”, sometimes using merely “Roche”, in an attempt to relate entirely separate and distinct companies that are Roche Switzerland, Roche Germany and Roche U.S.. Regardless of Amgen’s mischaracterizations, the relevant facts remain the same:

- Roche Switzerland has not and does not sponsor any of the U.S. clinical trials - including those in Massachusetts - related to the drug at issue in this action;
- Roche Switzerland has not and does not produce, manufacture or export to the U.S. the drug at issue in this action;
- Roche Switzerland has only intermittent contacts with Massachusetts, and is not registered to do business in Massachusetts; and
- Contrary to Amgen’s curiously misleading quotes from a 2002 opinion, no court in Massachusetts has ever exercised jurisdiction over Roche Switzerland, nor did a Court find that Roche Switzerland does business in Massachusetts.

Though Amgen can obtain every remedy to which it may be entitled in an action against Roche U.S., it nevertheless seeks to harass Roche Switzerland by trying to hale it into a court it did not expect and could not reasonably have expected to be brought to, and worse to force it to pay for an expensive and unnecessary discovery process. In fairness, given that at best, this case is based on speculation of what may happen possibly 1-2 years from now if the FDA approves CERA, the Court should refuse to exercise jurisdiction over Roche Switzerland and dismiss it from this action, with prejudice.

II. ARGUMENT

A. Roche Switzerland Is Not Subject To Specific Jurisdiction

Even under the legal scheme described by Amgen, Roche Switzerland is not subject to specific jurisdiction in Massachusetts. Amgen agrees that three tests must be satisfied to obtain jurisdiction over a defendant: “(1) the defendant must have ‘purposefully directed’ activities at the forum, (2) the claim must arise from or relate to those activities, and (3) the assertion of personal jurisdiction is not unreasonable and unfair.” *See* Amgen’s Opposition To Defendants’ Motions To Dismiss For Lack Of Personal Jurisdiction (And Alternative Request For Leave To Take Jurisdictional Discovery), dated April 25, 2006 (“Opp. Mem.”) at 7 and fn. 25. Amgen fails on the very first prong, rendering the other components moot.

Amgen recognizes the futility of its attempt to fit Roche Switzerland into the box of Massachusetts specific jurisdiction because it only raises one “fact” to support its contention: that Roche Switzerland is the supposed sponsor of clinical trials related to the drug at issue here, in Massachusetts. Opp. Mem. at 10. Unfortunately for Amgen, that “fact” is fiction. Amgen points the Court to the following web address:

http://www.roche-trials.com/patient/studies/drugplst_ro0503821.html, and states: “...Roche Switzerland is identified as the “sponsor” for such trials...” Opp. Mem. at 10 and fn. 46. Amgen is either mischaracterizing the website or just plainly careless, because Roche Switzerland is neither mentioned on that page, nor on any of the studies listed on that page. Rather, when each study’s link is followed, the companies listed as “sponsor” are either Hoffman-La Roche, Hoffman-La Roche Ltd. or Hoffman-La Roche Inc. Roche Switzerland is F. Hoffman-La Roche, Ltd. *See e.g.* <http://www.roche-trials.com/patient/trials/trial36.html>. Amgen is turning an American or British company into a Swiss. Furthermore, the website Amgen cites is maintained by a company called Centerwatch, not by Roche Switzerland, and it is imprecise as to the various

corporate entities. It merely seeks to convey that “Roche” is the company sponsoring the trials (as opposed to another company, such as Merck) and not the specific corporate Roche entity responsible for the trials in the various countries in which the trials are conducted. Most importantly, it is written for lay persons. The use of the term “sponsor” there is not as a term of art, but rather for lay persons, and Amgen’s attempt to link the word to the C.F.R. is unwarranted.

The truth is that all Roche-related clinical trials in the U.S. regarding CERA are sponsored by Roche U.S., including those in Massachusetts. All agreements, contracts and payments are between the local clinical trials physicians and Roche U.S. Roche Switzerland participates in the global process to create clinical trials, but leaves the actual contracting and management of the trials in the U.S. to Roche U.S. Roche Switzerland has no anemia related activity in Massachusetts whatsoever. It has not purposefully directed any activity at Massachusetts, and thus no claim can have arisen from any such activity. Asserting jurisdiction over Roche Switzerland would therefore be both unreasonable and unfair.

Amgen relies on *3D Systems, Inc. v. Aarotech Labs., Inc.*, 160 F.3d 1373 (Fed. Cir. 1998) as analogous to the present circumstances, and thus as support for jurisdiction. However, *3D Systems* supports Roche Switzerland’s position. There, a California plaintiff sued a West Virginia company. The communications sent from the W.V. defendant, Aeroflex, into California were offers to sell an allegedly infringing product, and thus the court ruled they were purposeful actions directly related to the patent litigation. However, the court **declined** to exercise jurisdiction over Aeroflex’s parent, an Oklahoma company. The situation is virtually identical here: Roche Switzerland does not make or sell anything in Massachusetts. It was Roche U.S. that sent the drug into Massachusetts for purposes of clinical trials required for FDA approval.

Just as the court in *3D Systems* refused to extend jurisdiction over a foreign corporate parent, this Court should refuse to extend jurisdiction over a truly foreign corporate sister located in Europe.

The undisputed facts are still that Roche Switzerland is not registered to do business in Massachusetts, does not manufacture, process, export or sell the drug at issue in Massachusetts and conducts *no* CERA-related business in Massachusetts. Roche Switzerland exercises control neither over the manufacture of the drug nor control where the U.S. Defendant distributes the drug. In short, Roche Switzerland has done nothing to give rise to any Amgen claim, and therefore Roche Switzerland should be dismissed, with prejudice.

B. Roche Switzerland Is Not Subject To General Jurisdiction

Even under the standard Amgen sets, there is no jurisdiction over Roche Switzerland as it has no “continuous and systematic” contacts with Massachusetts. Opp. Mem. at 6 and fn. 22. Amgen is correct when it states that general jurisdiction rests on the facts of each particular case (*Id.*) but incorrect in its application of that rule to the facts of **this** case.

For example, Amgen’s reliance on *Ciardi v. F. Hoffmann-La Roche, Ltd.*, 436 Mass. 53, 55, 762 N.E.2d 303, 306 (Mass. 2002) as support for personal jurisdiction is misguided, and by no means contradicts Roche Switzerland’s statement in its moving brief that neither this court, nor an earlier court, exercised jurisdiction over the foreign Roche defendants. The question of jurisdiction was held in abeyance until other issues were litigated, and the case eventually settled before any jurisdictional determination was rendered. Moreover, Amgen’s use of the phrase “the court found” is mistaken at best, as that language was clearly dicta; the court made no actual finding of fact. *See Ciardi v. F. Hoffmann-La Roche, Ltd.*, 436 Mass. 53, 55, 762 N.E.2d 303, 306 (Mass. 2002). Even were it otherwise, the court’s statement was based on information from years before that suit, making it far too remote and irrelevant to this action. Roche Switzerland

simply has not been found within the jurisdiction of any Massachusetts court and should not be now.

In addition, Amgen self-servingly writes that “[b]ecause Roche Switzerland chose to reveal so little to this Court about the nature and number of these contracts and agreements, one can assume that they must be substantial.” Opp. Mem. at 12. But exactly the opposite is true. Roche provided as complete information as it could that there are no other contacts, substantial or minor, with Massachusetts. As the burden is Amgen’s to provide a definite basis for jurisdiction, Amgen cannot “assume” otherwise.

Amgen has not refuted the fact that Roche Switzerland does not advertise in Massachusetts, does not have offices or property in Massachusetts, has no sales force in Massachusetts, no bank accounts or revenue from Massachusetts, and is party to only a few agreements with Massachusetts partners. In brief, Roche Switzerland does not affect the commerce of Massachusetts substantially, and it is not subject to general jurisdiction there. Roche’s intermittent and insubstantial contacts with Massachusetts should not subject it to being haled into a court in Massachusetts.

C. Jurisdiction Over Roche Switzerland Would Violate Due Process Notions Of Fairness

Amgen has not met its burden of showing continuous and systematic contacts between Roche Switzerland and Massachusetts, and so the Court need not go further. However, even if Roche Switzerland had such contacts, still this Court should not exercise jurisdiction over it because to do so would be unreasonable and unfair in violation of due process.

As discussed in Roche Switzerland’s moving papers, the Court must consider the five “gestalt” factors, and here they all “tip the constitutional balance” in favor of finding that jurisdiction does not comport with due process and “traditional notions of ‘fair play and

substantial justice.”’ *Nowak v. Tak How Invs., Ltd.*, 94 F.3d 708, 717 (Fed. Cir. 1996) (citing *Int’l Shoe Co. v. State of Wash.*, 326 U.S. 310, 320 (1945)).

First, being forced to litigate in a Massachusetts court would unduly burden Roche Switzerland, as it is both far away and never reasonably expected to be brought into a Massachusetts court. Amgen’s attempt to turn this point into an argument over venue, as opposed to jurisdiction, is mistaken, as the question is not whether this district is more or less suitable than another U.S. federal district, but rather whether **this** district has jurisdiction over this defendant. That question is separate and distinct, and the answer is no. The burden of being in a foreign country, appreciably far from its center of gravity, in a litigation in a state toward which it has not purposefully directed its commerce, is unreasonable and unfair, and this factor weighs against exercising jurisdiction.

Second, Massachusetts has no particular interest in adjudicating this action. Amgen can proceed against Roche U.S. and receive whatever remedy it may be entitled to, but Massachusetts has no interest in having Roche Switzerland be part of this action. Indeed, Amgen itself is not a Massachusetts company. Roche Switzerland is not a Massachusetts company. In fact, none of the entities in this case are Massachusetts companies. Therefore this factor again tips the scale against jurisdiction.

Third, while Amgen may have a distinct interest in obtaining relief, it has no such interest in obtaining it from *Roche Switzerland*, and no right to be in Massachusetts. Any relief it may need can be obtained as against the Roche U.S. defendant. Roche U.S. is the entity that sponsors clinical trials in Massachusetts with respect to CERA. Moreover, contrary to Amgen’s assertion to the contrary, it is Roche U.S. that contracts with physicians and hospitals to perform services in Massachusetts regarding CERA. Amgen’s interests would be fully served by litigation with

Roche U.S., without need for the heavy burden Roche Switzerland would bear were it forced to appear. Thus this factor also weighs against exercising jurisdiction.

Fourth, Amgen again confuses jurisdiction with venue, arguing that this Court should hear any action regarding this technology rather than another district court. This is not the issue before the Court. The issue is whether Roche Switzerland is within the jurisdiction of this court, and the interstate judicial system's interest in obtaining efficient resolution of the controversy is satisfied by the presence of the Roche U.S. defendant. There is simply no need or reason for Roche Switzerland to be here, and to force it to be here would be unfair and unreasonable. This fact likewise goes against Amgen and for Roche Switzerland.

Fifth and finally, it is a misstatement to assert that Roche Switzerland knew that the drug at issue would be administered to residents of any given state, including Massachusetts. Amgen seems to have just made that up, as it cites no support for this statement. The placement and direction of clinical trials in the US regarding CERA are solely under the control of Roche U.S. To thus force Roche Switzerland into court in Massachusetts would send a message to similar foreign companies that even those that take steps to keep at arms length from any given state, and deliberately associate with sister companies in the U.S. will nonetheless be subject to lawsuits in those states, potentially driving them away.

Amgen's reliance on *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558 (Fed. Cir. 1994) is misplaced, as it is easily distinguished. There, the foreign entity **directly sold the product to its U.S. distributor who sold the product in that same state, Virginia.** Here, Roche Switzerland is not selling anything, it is not delivering anything, and its contact is with its U.S. sister company **in New Jersey.** The cases are entirely dissimilar.

Accordingly, each of the factors weigh against the exercise of jurisdiction and this Court should dismiss the complaint as against Roche Switzerland.

D. Discovery Is Not Needed And Should Not Be Granted

Amgen's alternative request for jurisdictional discovery should be denied. Indeed, in the very case upon which upon which Amgen relies, *U.S. v. Swiss American Bank, Ltd.*, 274 F.3d 610 (1st Cir. 1999), the court **denied** the request for jurisdictional discovery. As Amgen quotes: "a diligent plaintiff who sues an out-of-state corporation who makes out a colorable case for the existence of *in personam* jurisdiction *may* well be entitled to a modicum of jurisdictional discovery..." (emphasis in original). Opp. Mem. at 17, fn. 71. Here, as described above, Amgen has not met that burden, is not a diligent plaintiff, and has not made out a colorable claim for the existence of personal jurisdiction.

What Amgen **has** done is blur the facts as among Roche Switzerland, Roche U.S. and Roche Germany. Roche Germany, not Roche Switzerland, manufactures the drug at issue. Roche Germany, not Roche Switzerland, sends the drug at issue to New Jersey. Those facts suggest at best that if this case should be anywhere, it should be in New Jersey and not include Roche Switzerland. Roche U.S. decides where the drug is sent, contracts for trials and use of the experimental drug in Massachusetts, pays for those contracts in Massachusetts and sponsors and directs the programs in Massachusetts, not Roche Switzerland. Roche Switzerland simply does not have the contacts sufficient to support even a colorable claim against it in Massachusetts.

The Federal Circuit approved of the lower court's denial of a request for discovery in a similar action in *Hockerson-Halberstadt, Inc. v. Propet USA, Inc.*, 62 Fed. Appx. 322 (Fed. Cir. 2003). There, co-defendant Costco filed a motion to dismiss for lack of personal jurisdiction, much as Roche Switzerland has done here. There, as here, the plaintiff opposed and in the alternative asked for discovery. The district court granted Costo's motion and dismissed the suit

against it. *Id.* at 326. Upon review of the lower court’s decision, the Federal Circuit noted that Costco:

never operated any warehouse locations in Louisiana and has no bank accounts, property, offices, agents, or employees in that state. It also has no inventory or sales records in Louisiana. Finally, Costco is not registered to do business in Louisiana and does not have an agent for service of process in Louisiana. . . . Between November of 1998 and April of 2000, Costco shipped a total of \$32,252.32 worth of merchandise into Louisiana pursuant to orders made through the website. . . . None of the e-commerce sales into Louisiana were sales of the alleged infringing footwear. *Id.* at 335.

The court went on to hold that Costco’s “contacts in Louisiana were not so substantial and of such a nature as to justify the exercise of general jurisdiction over it.” *Id.* at 337. On the issue of discovery, the Court found that “[w]hen the lack of personal jurisdiction [sic] is clear, like in this case, further discovery serves no purpose and should be denied.” *Id.* at 338. Likewise here, where the lack of personal jurisdiction is clear, further discovery would only be an undue burden on Roche Switzerland.

Finally, as stated in Defendants’ concurrently filed reply briefs, Amgen’s request for broad discovery is nothing more than a transparent attempt to harass Roche U.S.’s current efforts to gain FDA approval for CERA. As Amgen should have learned from this Court once before, this requested discovery constitutes the kind of resource draining distraction that 35 U.S.C. § 271(e)(1) was designed to eliminate. *See Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 112-13 (D. Mass. 1998) (Young, C.J.).

Accordingly, the Court should not place the expensive and heavy burden of jurisdictional discovery upon Roche Switzerland, but rather should dismiss the action, with prejudice.

III. CONCLUSION

Roche Switzerland has done nothing to merit being forced into litigation in Massachusetts, neither related to the drug at issue nor in respect of general contacts. Instead it has deliberately structured itself to work with a sister company in the U.S., who is already party to this litigation. Amgen should not be allowed to unfairly burden Roche Switzerland with this action when everything it might want it can get from Roche U.S., and when including Roche Switzerland would violate Constitutional Due Process. This Court should dismiss Roche Switzerland.

DATED: Boston, Massachusetts
May 1, 2006

F. HOFFMANN-LA ROCHE LTD,
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HOFFMANN-LA ROCHE INC.

By its attorneys,

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/s/ Julia Huston_____

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