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 ROCHE DIAGNOSTICS GMBH'S REPLY MEMORANDUM IN FURTHER SUPPORT OF ITS MOTION TO DISMISS

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I. PRELIMINARY STATEMENT

As Amgen admits in its opposition, it has the burden of demonstrating a *prima facie* case of personal jurisdiction over Roche Diagnostics GmbH ("Roche Germany").[1] Amgen has failed for at least the following reasons. Amgen's only basis for claiming that this Court has personal jurisdiction over Roche Germany is to search back over 20 years to when Roche Germany, then known as Boehringer Mannheim, GmbH ("BMG") executed a contract in Boston with Genetics Institute over the manufacture of EPO. However, a 20 year old business transaction does not amount to the "continuous and systematic contacts" necessary to support personal jurisdiction.

Amgen's arguments that this transaction during the 1980s form the basis of specific jurisdiction are specious. Amgen's current declaratory judgment claims for patent infringement arise from Roche U.S.'s current attempt to gain regulatory approval of CERA, which is a completely different molecule from EPO. CERA is not a generic version of EPO. As Amgen suggests in its opposition brief to Roche's motion to dismiss for lack of subject matter jurisdiction, CERA appears to be a superior drug to EPO.[2] CERA was not the subject of the 20 year old transaction with Genetics Institute. Moreover, Roche Germany has never sold EPO in the U.S. and has no intention to do so. Therefore, Amgen's arguments for specific jurisdiction are unavailing and simply the result of Amgen's wishful thinking.

Realizing that it has failed to meet its burden on this issue, Amgen instead seeks leave to conduct massive international discovery on Defendants involving at least two continents and three countries. However, as also explained in Defendants' Reply Memorandum in further

[1] Defendants have filed a separate reply brief with respect to its Motion to Dismiss F. Hoffman-La Roche Ltd. ("Roche Switzerland").

[2] *See e.g.*, Amgen's Opposition Brief, Docket No. 53-1, footnote 9 ("As Dr. Iain McDougall explained at Roche's November 17, 2003 Inventor Conference Call, '[o]n the left there you see CERA which is a much, much larger molecule, with a huge big polymer chain to the left-hand side but yet retaining the receptor-binding component of the molecule obviously in order to stimulate [erythropoiesis]....'.").

support of their motion to dismiss for lack of subject matter jurisdiction, filed concurrently, Amgen's request is nothing more than a transparent attempt to delay resolution of this issue and harass Roche U.S.'s efforts to gain FDA approval for CERA.

II. ARGUMENT

A. Amgen Has Failed To Meet Its Burden Of Proving Specific Or General Personal Jurisdiction

Amgen's whole argument regarding personal jurisdiction over Roche Germany is based on a business transaction, first negotiated in 1984, and resulting in a license agreement in October 8, 1985, between Genetics Institute ("GI") and Roche Germany's predecessor company, Boehringer Mannheim GmbH ("BMG") ("License Agreement").

This License Agreement, which was executed in Boston, provided that BMG would fund GI to conduct a research project using recombinant DNA technology for producing EPO. *See Trustees of Columbia University v. Boehringer Mannheim, GmbH*, 1995 WL 591291, *1 (D. Mass. 1995) (Gertner, J.). The agreement also called for commercial scale up of EPO by GI, as well as a transfer of EPO to BMG. *Id.* A further supply agreement between the parties was executed in January 11, 1988, where BMG agreed to purchase certain amounts of EPO produced by GI in Massachusetts. *Id.* at *2.

In 1997, Roche acquired BMG, which then became Roche Germany (Reply Ex. 1).[3] Moreover, in 1992, American Home Products (AHP), a company based in Madison, N.J., acquired a 60% share of Genetics Institute, which later became a wholly owned subsidiary of AHP in December 1996 (Reply Ex. 2 at 3). In March 2002, AHP changed its corporate name to

[3] "Reply Ex." refers to exhibits attached to the accompanying Reply Declaration of Howard S. Suh.

Wyeth. *Id.* As of 2003, Roche Germany stopped all payments on the License Agreement with Massachusetts, and instead transferred funds to Wyeth in Paoli, Pennsylvania.[4]

As these facts demonstrate, Roche Germany's contacts with Massachusetts center around a business transaction that took place over 20 years ago. While there were amendments to that License Agreement between the years 1988-1996, this still shows an absence of conducting business in Massachusetts for at least 10 years. Moreover, Roche Germany no longer makes any payments to Massachusetts on this License Agreement, but directs these fees to G.I.'s successor, Wyeth, in Pennsylvania.

Under these circumstances, where the alleged transaction with the forum state has taken place several years before the filing of the complaint, courts have routinely found a lack of "continuous and systematic contacts" to support personal jurisdiction. *See Morris Material Handling, Inc. v. KCI Konecranes PLC*, 334 F. Supp. 2d. 1118, 1121 (E.D. Wisc. 2004) (Purchasing business in forum state **7 years** ago by Finnish corporation was not sufficient contacts to satisfy personal jurisdiction); *Star Technology v. Tultex Corp.*, 844 F. Supp. 295, 298 (N.D. Tex. 1993) (Non-resident attorney's contact with forum state **10 years** earlier did not make him amenable to general personal jurisdiction); *U.S. v. Subklew*, 2001 WL 896473, *4 (S.D. Fla. 2001) (In denying personal jurisdiction, court stated that "[t]he government's allegations that Subklew was a resident of Florida between 1987 and 1994 and conducted general carpentry work out of his home during an unspecified portion of that period, are insufficient to cause the Court to look past the fact that Subklew has had no contacts with Florida since 1995 [**6 years** before filing of complaint]"); *Sanderson v. Spectrum Labs, Inc.*, 227 F. Supp. 2d 1001, 1013 (N.D. Ind. 2000)

[4] Roche Germany intends to submit a forthcoming declaration attesting to this fact. A declaration could not be secured today because of the May Day holidays in Europe, and Defendants regret any inconvenience this may cause the Court and Amgen.

("**Eleven-year old** study into the effectiveness of magnetic water treatment, this is insufficient to confer personal jurisdiction.") (emphasis added); *K.C.P.L., Inc. v. Nash*, 1998 WL 823657, *9 (S.D.N.Y. 1998) (no personal jurisdiction where defendant had no contacts with the forum state in the past **3 years**) (emphasis added); *Database America, Inc. v. Bellsouth Advertising & Publishing Corp.*, 835 F. Supp. 1195, 1214-1215 (D.N.J. 1993) (no personal jurisdiction because mailing list was not purchased since 1988 [**5 years** prior to the case]); *Riga International Corp. v. Alpern*, 1987 WL 28412, *1 (N.D. Ill. 1987) (In finding no personal jurisdiction, "[n]either Gridcomm nor defendant conducts any business in Illinois or has any offices or property in Illinois, and defendant has not been physically present in Illinois for **several years**.") (emphasis added).

Amgen attempts to resurrect the relevancy of these stale transactions with GI by arguing that these activities actually provide a basis for specific jurisdiction. Not so. Specific jurisdiction requires, among other things, that the cause of action either directly arises out of or is directly related to defendant's forum based contact. *See Harlow v. Children's Hospital*, 432 F.3d 50, 61 (1st Cir. 2005). As the First Circuit noted in *Harlow*, this requirement is "not an open door; it is closely read, and it requires a showing of material connection." *Id.* The Court went on and stated that:

> This court "steadfastly reject[s] the exercise of personal jurisdiction whenever the connection between the cause of action and the defendant's forum-state contacts seems attenuated and indirect." *Id.* at 1089 (citing *Donatelli*, 893 F.2d at 463). "Instead, the defendant's in-state conduct must form an 'important, or [at least] material, element of proof' in the plaintiff's case." *Id.* (alteration in original) (quoting *Marino v. Hyatt Corp.*, 793 F.2d 427, 430 (1st Cir.1986)). A broad "but-for" argument is generally insufficient. Because "'but for' events can be very remote, . . . due process demands something like a 'proximate cause' nexus." *Cambridge Literary Props.*, 295 F.3d at 65. And although "strict adherence to a proximate cause standard in all circumstances is

> unnecessarily restrictive," in most cases "the proximate cause standard better comports with the relatedness inquiry because it so easily correlates to foreseeability, a significant component of the jurisdictional inquiry." *Nowak v. Tak How Invs., Ltd.*, 94 F.3d 708, 715 (1st Cir. 1996). "A 'but for' requirement . . . has in itself no limiting principle; it literally embraces every event that hindsight can logically identify in the causative chain." *Id.* In sum, although proximate causation is not a per se requirement of specific jurisdiction, its presence or absence is still important. *Id.* at 715-16.

Id.

Here, Amgen has brought a declaratory judgment action based on allegations that Roche U.S.'s attempts to gain FDA approval for its product, CERA, constitute an imminent threat of patent infringement. On the other hand, the 1986 License Agreement involved the production and transfer of EPO, not the accused infringing product CERA. As discussed in Defendants' Motion To Dismiss For Lack Of Subject Matter Jurisdiction and Failure to State a Claim, CERA is a completely different molecule from EPO, having almost twice the molecular weight and physical size of EPO. CERA has a considerably longer circulating lifetime in the human body, is more soluble, and its formulation is more stable at room temperature than Amgen's EPO product. Unlike EPO, which is quickly internalized and degraded after binding to the receptors involved in stimulating red blood cell production, CERA has a greatly reduced affinity to the receptors. This reduced affinity at the receptor allows CERA to stimulate red cell production without immediate degradation. CERA's distinct molecular interaction has an essential role in providing targeted, stable and sustained control of anemia.

Amgen may try to argue that its patents, which are directed to EPO, are infringed because CERA somehow "contains" EPO. However, this strained infringement theory would still not warrant specific jurisdiction based on the 1986 License Agreement. The Roche product currently under review by the FDA is not any reagent, but a finished pharmaceutical composition. If in the

future, Roche U.S.'s CERA is approved by the FDA, Roche U.S. will not have approval for EPO. Simply put, Amgen's Complaint and cause of action do not arise from the transfer of EPO from Massachusetts to BMG in the 1980s under the License Agreement. Clearly, the BMG transaction that took place 20 years ago was not the 'proximate cause' for Roche U.S.'s efforts to gain FDA approval of CERA. Instead, Amgen presents, at best, an attenuated argument that "but-for" the 1986 transaction involving EPO, there would be no CERA. However, not only is this assertion factually incorrect, but as the First Circuit and others have recognized, such "but-for" events are too remote and speculative to support specific personal jurisdiction. *See Harlow*, 432 F.3d at 63-64. ("Harlow's 'but-for' theory - that but for the referral from a Maine pediatrician, the harm would never have happened - is insufficient to give Maine specific jurisdiction over the Hospital."); *Graphic Controls Corp. v. Utah Medical Products*, 149 F.3d 1382, 1388 (Fed. Cir. 1998) (No specific jurisdiction because of lack of nexus between business transactions and cause of action).

By entering into a contract with a Boston company 20 years ago, Roche Germany's predecessor company could never have reasonably expected that a new chemical entity, CERA, which was developed several years later, would be sold in this forum state. To expect otherwise would go against 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)).

After all, being forced to litigate in a Massachusetts court would unduly burden Roche Germany, as it is both far away and never expected to be brought into a Massachusetts court. The burden to be 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.

Moreover, even under Amgen's allegations in its Complaint, Roche Germany is not imminently marketing, selling or using CERA in Massachusetts, and the only Roche entity that may in the future receive FDA approval to do so is Roche U.S. Amgen can proceed against Roche U.S. and receive whatever remedy it may be entitled to, but Massachusetts has no interest in having Roche Germany be part of this action.

While Amgen may have a distinct interest in obtaining relief, it has no such interest in obtaining it from Roche Germany, as any relief it may need can be obtained as against the Roche U.S. defendant. Roche U.S. is the entity that sponsors the clinical trials in Massachusetts regarding CERA. Roche U.S. is the entity that contracts with physicians and hospitals to perform services in Massachusetts on CERA. Amgen's interests may be fully served by litigation with Roche U.S., without need for the heavy burden Roche Germany would bear were it forced to appear.

Amgen's citation to a Roche Germany's 2001 Answer to an Amended Complaint in the *Columbia* case, in which Roche Germany stated that it "is transacting business in this district," is equally unavailing. First, Amgen does not tell the Court that Roche Germany was then answering allegations from a complaint that was first filed 8 years earlier in 1993 over the events surrounding the 1986 License Agreement. Therefore, as stated above, the business transactions had by that time terminated several years earlier. Moreover, Roche Germany only made an appearance in that case after vigorously challenging personal jurisdiction. *See Trustees of Columbia University v. Boehringer Mannheim, GmbH*, 1995 WL 591291, *1 (D. Mass. 1995) (Gertner, J.). While the Court did find personal jurisdiction over Roche Germany in that case, it

did so under completely different facts. The plaintiffs in *Columbia* asserted that BMG induced the infringement of plaintiff's patents by contracting with GI to make EPO. *Id.* Therefore, in that case, the 1986 License Agreement did form the basis of the underlying cause of action to support specific personal jurisdiction and was indeed one of the alleged acts of induced infringement.

Here, as stated above, Amgen's count for declaratory judgment arises from Roche U.S.'s attempts to receive FDA approval for CERA, which is a completely different molecule from EPO. The 1986 License Agreement regarding the production of EPO has no nexus with the allegations of the current lawsuit.

B. Amgen's Request For Discovery Should Be Denied

As explained in detail in Defendants' Reply Memorandum in further support of its motion to dismiss for lack of subject matter jurisdiction and failure to state a claim ("Defendants' DJ Reply Brief"), Amgen's request for broad discovery is nothing more than a transparent attempt to harass and distract Roche U.S.'s current efforts to gain FDA approval of CERA. As argued in Defendant's DJ Reply Brief, this requested discovery constitutes the kind of resource draining tactics 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.). Defendants believe that it is better practice to dismiss this case based on a lack of subject matter jurisdiction, rather than allow Amgen free reign to conduct such large scale discovery. Moreover, Amgen should not be rewarded for its blatant acts of forum shopping, as it clearly chose this forum to bring its lawsuit, only to then rush to the ITC upon learning that Defendants' moved to dismiss. Therefore, Amgen's request for discovery should be denied and Roche Germany should be dismissed from this case.

III. CONCLUSION

Based on the foregoing, Defendants respectfully request that the Court grant its motion to dismiss Roche Diagnostics GmbH from this case for lack of personal jurisdiction.

DATED: Boston, Massachusetts
May 1, 2006

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