UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	Civil Action No.: 05 Civ. 12237 WGY
v.	)	
	)	
F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GMBH, AND HOFFMANN LA ROCHE INC.,	)	
	)	
Defendants.	)	

AMGEN'S OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS FOR LACK OF PERSONAL JURISDICTION (AND ALTERNATIVE REQUEST FOR LEAVE TO TAKE JURISDICTIONAL DISCOVERY)

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I. INTRODUCTION

In this action, Amgen seeks a declaratory judgment that the importation, use, offer for sale and sale in the United States of the Defendants' "CERA" drug product containing recombinant human EPO (to which the Defendants have attached a biologically inert polymer called "polyethylene glycol," or "PEG") will infringe certain claims in six Amgen patents.[1]

Last November, it appeared that Defendants were completing their clinical tests of PEG-EPO and would soon seek approval from the FDA to market the product in the United States. Amgen filed this action against those Roche companies that had been publicly identified as manufacturing, importing and administering PEG-EPO to patients in the United States, including in Massachusetts. Based on Defendants' public descriptions of their PEG-EPO product and its reported effects on patients, Amgen believes that the importation, use, and sale of PEG-EPO by those companies will infringe Amgen's patents.

Amgen named Roche Diagnostics GmbH ("Roche Germany") as a defendant because Roche Germany purchased a recombinant human EPO-producing cell line from a Massachusetts-based company, Genetics Institute, and has been using those cells to produce recombinant human EPO ever since, and the publicly available evidence indicated that Roche Germany was adding PEG to the recombinant human EPO produced by those cells and shipping that PEG-EPO to the United States (this latter fact has now been confirmed by the Defendants in their motions to dismiss). Amgen named Hoffmann La Roche, Inc. ("Roche US"), a company in New Jersey, as a defendant because Roche US identifies itself as the "U.S. prescription drug unit of the Roche Group," *i.e.*, the company that distributes the Roche Group's pharmaceutical products in the U.S., and it was reasonable to believe that this included PEG-EPO (this has also now been

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[1] The Roche defendants have referred to this "pegylated" EPO product at various times as "CERA," "Ro50-3821," and/or "R744"; it is referred to herein as "PEG-EPO" or "pegylated EPO."

confirmed by the Defendants in their motions). Amgen named F. Hoffmann-La Roche Ltd. ("Roche Switzerland"), a Swiss company, as a defendant because Roche Switzerland serves as the organizational unit for the Roche Group's pharmaceutical operations and had publicly identified itself as the sponsor of Roche's clinical trials in which PEG-EPO was being administered to patients in the United States (including in Massachusetts).[2]

Roche Switzerland and Roche Germany (collectively "the foreign Roche defendants") have moved to dismiss this action under Fed. R. Civ. P. 12(b)(2) for lack of personal jurisdiction. In their motion papers,[3] the foreign Roche defendants claim to have had very little contact with Massachusetts. But the public record, and the admissions by the foreign Roche defendants in their motion papers, contradict that assertion. As noted above, Roche Germany (which was formerly known as Boehringer Mannheim GmbH) has been transacting business involving recombinant human EPO (and cell lines that produce that EPO) under development and licensing agreements with Genetics Institute, a company headquartered in Massachusetts, since the early 1980's. In the mid-1980's, Genetics Institute transferred substantial amounts of recombinant human EPO, as well as the cell lines that produce that EPO, to Roche Germany, and over the years, Roche Germany has produced recombinant human EPO using those cells and has paid Genetics Institute more than $100 million under those agreements.

The public record also indicates (and the Defendants now admit) that the PEG-EPO that Roche Germany has been manufacturing and shipping into the United States for the last several years has been administered to patients in Massachusetts. And both of the foreign Roche

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[2] Amgen is concurrently filing a First Amended Complaint to reflect the fact that on April 19, 2006, the Defendants filed a Biologic License Application ("BLA") with the FDA seeking approval to market their PEG-EPO product, but believes that the foreign Roche defendants were subject to personal jurisdiction in Massachusetts as of the filing date of the original Complaint (November 8, 2005).

[3] Docket Nos. 39 and 40 (the "Roche Switzerland Memo" and "Roche Germany Memo," respectively).

defendants admit that they have contracts with Massachusetts companies, that Roche Switzerland sponsors clinical trials for experimental drugs in Massachusetts, and that both Defendants regularly send their employees into Massachusetts for business purposes (indeed, on the last page of its memorandum, Roche Switzerland admits that at least ***137*** of its employees came to Massachusetts ***in 2005 alone*** to conduct such business).

Amgen need only make a *prima facie* showing that defendants are subject to personal jurisdiction to defeat the instant motions to dismiss. Here, the public record and the admissions by the foreign Roche defendants regarding their contacts with Massachusetts are sufficient to satisfy this *prima facie* requirement for both specific and general personal jurisdiction. Both of the foreign Roche defendants have conducted substantial, regular, and systematic activities in Massachusetts, and much of that activity is related to the recombinant human EPO that is the basis for the current cause of action.[4]

II. ARGUMENT

Because the foreign Roche defendants have challenged personal jurisdiction, Amgen bears the burden of establishing that they are subject to personal jurisdiction in this Court.[5] In a patent case such as this, the law of the Federal Circuit applies in resolving such motions.[6] The

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[4] Alternatively, if the Court believes that the facts currently of record are not sufficient to determine that the foreign Roche defendants are subject to personal jurisdiction here, Amgen requests that it be granted leave to take discovery from the Defendants to supplement that record. The motion papers raise many questions about the scope and purpose of their business activities in Massachusetts, and those questions cannot currently be answered because the foreign Roche defendants have not been forthcoming in disclosing their contacts with Massachusetts. Amgen should be permitted to pursue jurisdictional discovery so as to provide this Court with a complete factual record.

[5] *Daynard v. Ness, Motley, Loadholt, Richardson & Poole, P.A.*, 284 F. Supp. 2d 204, 211 (D. Mass. 2003) (Young, C.J.).

[6] *Deprenyl Animal Health, Inc. v. Univ. of Toronto Innov. Found.*, 297 F.3d 1343, 1348 (Fed. Cir. 2002). In their motion papers, Defendants rely on a series of First Circuit cases to support their claims for lack of personal jurisdiction. *See, e.g.,* Roche Switzerland Memo at pp. 9-13 and Roche Germany Memo at pp. 5-14. Defendants' reliance on First Circuit law is misplaced given that Federal Circuit law applies to motions to dismiss for lack of personal jurisdiction in patent cases. *Hildebrand v. Steck Mfg. Company,*

Federal Circuit applies a "*prima facie*" test to such motions, whereby "a plaintiff need only to make a *prima facie* showing that defendants are subject to personal jurisdiction."[7]

A. The legal standards for personal jurisdiction

A two-prong inquiry governs whether this Court may properly exercise personal jurisdiction over the foreign Roche defendants. First, each Defendant must be amenable to process in Massachusetts. Second, the Court's exercise of personal jurisdiction over the Defendant must comply with the requirements of federal Due Process as delineated in *International Shoe Co.* [8] and its progeny.[9] Alternatively, because Amgen's claims against the foreign Roche defendants arise under federal law,[10] if either defendant is beyond the jurisdictional reach of any single state, this Court may nevertheless exercise jurisdiction over that defendant if its contacts with the nation as a whole are sufficient to satisfy Due Process.[11]

1. Amenability to service of process

Service of process in a federal action is governed generally by Fed. R. Civ. P. 4. A defendant is amenable to service if it "could be subjected to the jurisdiction of a court of general jurisdiction in the state in which the district is located."[12] As the Federal Circuit has explained, "[s]atisfaction of this standard may be attained in a variety of ways."[13]

Inc., 279 F.3d 1351, 1354 (Fed. Cir. 2002) ("We apply Federal Circuit law to determine whether the district court properly exercised personal jurisdiction over out-of-state defendants in patent infringement cases."); *Electronics For Imaging, Inc. v. Coyle*, 340 F.3d 1344, 1348 (Fed. Cir. 2003) (finding that the district court erred by applying Ninth Circuit law to a motion under Fed. R. Civ. P. 12(b)(2) in a declaratory judgment action brought against an out-of-state patentee).

[7] *Elecs. For Imaging, Inc. v. Coyle*, 340 F.3d 1344, 1349 (Fed. Cir. 2003).

[8] *International Shoe Co. v. Washington*, 326 U.S. 310 (1945).

[9] *LSI Indus. Inc. v. Hubbell Lighting, Inc.*, 232 F.3d 1369, 1371 (Fed. Cir. 2000).

[10] The Patent Act, 35 U.S.C. § 1 *et seq.*

[11] *See* Fed. R. Civ. P. 4(k)(2); *Cochran Consulting, Inc. v. Uwatec USA, Inc.*, 102 F.3d 1224, 1232 (Fed. Cir. 1996); *U.S. v. Swiss American Bank, Ltd.*, 116 F. Supp. 2d 217, 220 (D. Mass. 2000) (Young, C.J.).

[12] Fed. R. Civ. P. 4(k)(1)(A).

[13] *LSI Indus.*, 232 F.3d at 1371.

Massachusetts has at least two different statutes under which an out-of-state defendant may be amenable to service of process: a "doing business" statute[14] and a "long arm" statute.[15] Section 38, the "doing business" statute, allows service of process on out-of-state defendants who "engage in" or "solicit" business in Massachusetts:

> In an action against **a foreign corporation**, except an insurance company, which has a usual place of business in the commonwealth, or with or without such usual place of business, **is engaged in or soliciting business in the commonwealth,** permanently or temporarily, service may be made in accordance with the preceding section relative to service on domestic corporations in general, instead of upon the state secretary under section 15.10 of subdivision A of Part 15 of chapter 156D.[16]

For service to be proper under section 38, the defendant's business activities must "affect the commerce of Massachusetts substantially."[17] The cause of action need not relate to the defendant's activities in Massachusetts.[18]

A defendant may also be amenable to process, and thus subject to "specific" personal jurisdiction, under the Massachusetts "long-arm" statute, which allows service of process on out-of-state defendants for causes of action arising from in-state business activity:

> A court may exercise personal jurisdiction over a person, who acts directly or by an agent, as to a cause of action in law or equity arising from the person's

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[14] Mass. Gen. Laws Ann., ch. 223, § 38.

[15] Mass. Gen. Laws Ann., ch. 223A, § 3.

[16] Mass. Gen. Laws. Ann., ch. 223, § 38 (emphases added). The "preceding section," § 37, provides: "In an action against a domestic corporation other than one mentioned in the preceding paragraph, service shall be made upon the president, treasurer, clerk, resident agent appointed pursuant to section 49 of chapter 156D, cashier, secretary, agent or other officer in charge of its business, or, if no such officer is found within the county, upon any member of the corporation." Mass. Gen. Laws. Ann., ch. 223, § 37.

[17] *Walsh v. National Seating Co., Inc.*, 411 F. Supp. 564, 574 (D. Mass. 1976).

[18] *Id.* at 575 ("where the activities of the corporation had a sufficiently substantial impact on the Commonwealth, the connection between the cause of action and the activities need not be present"); *Campbell v. Frontier Fishing & Hunting, Ltd.*, 405 N.E.2d 989, 991 (Mass. App. 1980) ("The fact that the cause of action arose in Canada does not defeat Massachusetts' claim to personal jurisdiction of Frontier under § 38, because this statute 'does not restrict service on resident agents of foreign corporations to causes of action arising within the Commonwealth.'" (quoting *Trojan Eng'g Corp. v. Green Mountain Power Corp.*, 200 N.E. 117, 120 (Mass. 1936)).

(a) transacting any business in this commonwealth; . . . .[19]

This Court need not, however, look solely at whether the literal requirements of the Massachusetts long-arm statute have been met. Because the foreign Roche defendants have not challenged whether they could have been properly served under the long-arm statute or § 38, and instead rest their motions on constitutional Due Process, the inquiry here turns on whether exercise of specific personal jurisdiction is consistent with Due Process.[20]

2. Due Process

Federal Due Process requires that a defendant have certain "minimum contacts" with Massachusetts such that litigating the suit here does not offend "traditional notions of fair play and substantial justice."[21] A defendant is subject to ***general*** personal jurisdiction in a forum where it has "continuous and systematic general business contacts."[22] In such a forum, a suit may be brought against a defendant "even when the cause of action has no relation to those contacts."[23] General personal jurisdiction rests on the facts of each particular case.[24]

In contrast, the Federal Circuit's Due Process test for ***specific*** personal jurisdiction in a

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[19] Mass. Gen. Laws Ann., ch. 223A, § 3. Despite the subsequent enactment of the Massachusetts long-arm statute, "Section 38 is independently viable and has not been supplanted by [the long-arm statute]." *Campbell,* 405 N.E.2d at 990. *See also* 16 James W. Moore, *Moore's Federal Practice* § 108.61 (3d ed. 2005).

[20] *Trintec Indus., Inc. v. Pedre Promotional Prods., Inc.*, 395 F.3d 1275, 1279 (Fed. Cir. 2005); *Elecs. For Imaging*, 340 F.3d at 1349-50; *Akro Corp. v. Luker*, 45 F.3d 1541, 1544 (Fed. Cir. 1995); *Freedom Wireless, Inc. v. Boston Commun. Grp., Inc.* 218 F. Supp. 2d 19, 23 (D. Mass. 2002) ("[B]ecause the Massachusetts Supreme Judicial Court has interpreted the state's long-arm statute as coextensive with the limits of due process, it is possible to "sidestep the statutory inquiry and proceed directly to the constitutional analysis."), quoting *Daynard v. Ness*, 290 F.3d 42, 52 (1st Cir. 2002); *Moldflow Corp. v. Simcon, Inc.*, 296 F. Supp. 2d 34, 39 (D. Mass. 2003) (same); *Cognex Corp. v. Lemelson Med., Educ. & Research Found., L.P.*, 67 F. Supp. 2d 5, 7 (D. Mass. 1999) (same).

[21] *International Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945).

[22] *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 416 (1984).

[23] *LSI Indus. Inc. v. Hubbell Lighting, Inc.*, 232 F.3d 1369, 1375 (Fed. Cir. 2000).

[24] *Id.* ("Neither the United States Supreme Court nor this court has outlined a specific test to follow when analyzing whether a defendant's activities within a state are 'continuous and systematic.' Instead, a court must look at the facts of each case to make such a determination.").

patent case is a three-prong test: (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.[25] A defendant has "purposefully directed" its activities to a forum state when it "deliberately has engaged in significant activities within a State, or has created continuing obligations between himself and residents of the forum."[26] "[E]ven a single act can support [specific] jurisdiction," so long as it creates a "substantial connection" with the forum, as opposed to an "attenuated affiliation."[27] If the plaintiff makes a *prima facie* showing of minimum contacts under the first two prongs of the test, the burden switches to the defendant to "present a compelling case that that the presence of some other considerations would render jurisdiction unreasonable."[28]

B. The foreign Roche defendants are subject to specific personal jurisdiction in Massachusetts

The activities of the foreign Roche defendants regarding the distribution and use of their recombinant human EPO product in Massachusetts are sufficient to satisfy the Due Process requirements for specific personal jurisdiction.

1. Roche Germany

Roche Germany is a German corporation with its headquarters in Mannheim, Germany and production facilities in Mannheim and Penzberg, Germany.[29] It is a wholly owned subsidiary of Roche Deutschland Holding GmbH, another German corporation, which is a wholly-owned subsidiary of F. Hoffmann-La Roche AG (located in Basel, Switzerland), which is itself a

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[25] *3D Systems, Inc. v. Aarotech Labs., Inc.*, 160 F.3d 1373, 1378 (Fed. Cir. 1998).
[26] Burger King Corp. v. Rudzewicz, 471 U.S. 462, 476 (1985).
[27] Burger King Corp. v. Rudzewicz, 471 U.S. at 475 & n. 18.
[28] *Akro Corp. v. Luker*, 45 F.3d 1541, 1546 (Fed. Cir. 1995), quoting *Burger King*, 471 U.S. at 477.
[29] *See* Roche Germany Memo at p. 3.

wholly-owned subsidiary of Roche Holding AG (also located in Basel, Switzerland).[30]

Roche Germany admits that it manufactures the pegylated recombinant human EPO that is the subject of this action, that it ships its PEG-EPO to the United States, and that its PEG-EPO is administered to patients in Massachusetts.[31]

Roche Germany and its declarant, Mr. Meisiek, also admit that "Roche Germany currently maintains a limited number of contracts with partners in Massachusetts" that are "all either licensing or research and development agreements pertaining to diagnostics or pharmaceuticals."[32] What Roche Germany and Mr. Meisiek don't tell this Court, but which was revealed in the *Trustees of Columbia University v. Roche Diagnostics GmbH* case[33] (a patent infringement case filed in 1993 that went to trial before Judge Gertner in 2001), is that among these "contracts with partners in Massachusetts" were several agreements[34] with Genetics Institute, Inc. (a company headquartered in Cambridge, Massachusetts) under which Genetics Institute transferred recombinant human EPO,[35] cell lines that produce that recombinant human EPO[36] and related know-how, and a license to patents directed to such technology, to Boehringer

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[30] *See* Declaration of Michael R. Gottfried, Esq. submitted herewith (hereinafter "Gottfried Decl."), Exh. A.

[31] *See* Roche Germany Memo at p. 4. Moreover, the results of Roche's preclinical studies on PEG-EPO were presented at scientific conferences in the United States by Roche scientists employed in Mannheim and Penzberg (*i.e.*, presumably employees of Roche Germany. *See* Gottfried Decl., Exh. L.

[32] Declaration of Martin Meisiek for Defendant Roche Diagnostics GmbH (Docket No. 47) at ¶ 14; Roche Germany Memo at pp. 1, 4.

[33] The Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH (formerly known as Boehringer Mannheim GmbH), Civ. No. 93-11512 NG (D. Mass.).

[34] *See* Gottfried Decl., Exh. B at pp. 780 and 782 and Exh. C at pp. 1026-27, 1042-45, and 1050-51 (Roche Germany entered into an initial licensing and development agreement with Genetics Institute in 1985 and supplemental agreements in 1988, 1991, and 1996).

[35] *See* Gottfried Decl., Exh. B at pp. 741-742, 743 and 746 and Exh. C at pp. 1043-44 (Genetics Institute shipped bulk human recombinant EPO to Roche Germany in November 1985 and from 1988-1991, which Roche Germany then used in clinical trials or sold).

[36] These were referred to as the "DN2-3α3" cell line. *See* Gottfried Decl., Exh. B at pp. 734-35 ("On March 4, 1986, GI transferred to Roche the EPO production clone DN2-3alpha3. DN2-3alpha3 is the only production clone used by Roche to make EPO for sale."), 743, 767, 791, and 805.

Mannheim GmbH, which later became Roche Germany.[37]

Over the subsequent years, Roche Germany has used those cell lines and know-how at its production facilities in Germany to produce the Defendants' second-best-selling drug,[38] a recombinant human EPO product generically known as "epoetin beta" that is sold in Europe and other non-U.S. markets as a pharmaceutical composition called NeoRecormon.[39] Roche Germany has paid Genetics Institute more than $100 million under those agreements.[40] The public record indicates that Roche Germany uses those same cells and methods to produce the "epoetin beta" contained in the Defendants' PEG-EPO product that is being administered to patients in Massachusetts and is accused of infringing Amgen's patents in this action.[41] Consequently, the current cause of action certainly relates to Roche Germany's purposeful contacts with Massachusetts (*i.e.*, its entry into and performance under the agreements with Massachusetts-based Genetics Institute and its use of the cell lines obtained from Genetics Institute to produce the product accused of infringement here).

Roche Germany's challenge to specific jurisdiction is based on its assertion that it has "no control over where the U.S. Defendant, [Roche US], distributes [PEG-EPO]."[42] However, the touchstone of the specific jurisdiction analysis regarding this issue is whether Roche Germany should have reasonably expected that the PEG-EPO would be used in Massachusetts,

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[37] *See* Gottfried Decl., Exh. C at pp. 996-997 and 1005 and Exh. D.

[38] *See* Gottfried Decl., Exh. E at p. 8 (showing NeoRecormon sales at 2.25 billion Swiss Francs, making it Roche's second-best-selling drug).

[39] *See* Gottfried Decl., Exh. F (a finding by the European Agency for the Evaluation of Medicinal Products that NeoRecormon is epoetin beta, a recombinant human EPO).

[40] *See* Gottfried Decl., Exh. B at pp. 796-799 and 814 (Roche Germany paid Genetics Institute more than $100 million dollars for EPO made by Genetics Institute and as royalties on the resale of that EPO).

[41] *See* Gottfried Decl., Exh. G (showing that medical institutions around the U.S. (including the National Cancer Institute and the Dana-Farber Cancer Institute) define the Defendants' PEG-EPO product ("Ro50-3821") as "methoxypolyethylene glycol epoetin beta").

[42] Roche Germany Memo at p. 13.

such that it would have fair warning that its activities might subject it to litigation in this forum.[43] It is inconceivable that Roche Germany would not have known from the beginning that the PEG-EPO it has been shipping to its partner Roche US in New Jersey was destined for use in clinical trials being conducted in various States, including Massachusetts. At most, Roche Germany would only have had to look on the Roche Switzerland website to determine that its PEG-EPO product was being sent into Massachusetts and administered to Massachusetts residents.

Roche Germany has engaged in substantial activities within Massachusetts that are directly related to the current cause of action. This is sufficient to satisfy the Federal Circuit's test for specific jurisdiction.

2. Roche Switzerland

The Defendants filed for approval to administer PEG-EPO to patients in the U.S. in 2001.[44] On their website (www.roche-trials.com/patient/studies/drugplst_RO0503821.html), the Defendants identify eleven PEG-EPO clinical trials conducted in Massachusetts, beginning in 2002.[45] On the website, Roche Switzerland is identified as the "sponsor" for such trials, *i.e.*, the company that "takes responsibility for and initiates [the] clinical investigation."[46] When the data from these PEG-EPO clinical trials was presented to the medical community, representatives from Roche Switzerland came to the U.S. to present the data,[47] and last week, the Defendants

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[43] *World-Wide Volkswagen Corp. v. Woodson*, 100 S.Ct. 559, 567 (1980) (adopting the "stream-of-commerce" theory); *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1565 (Fed. Cir. 1994) (adopting the stream-of-commerce test for specific jurisdiction in patent cases).

[44] *See* Declaration of Iris Kingma-Johnson in Support of [the Roche Defendants'] Motion to Dismiss for Lack of Subject Matter Jurisdiction and Failure to State a Claim for Which Relief May Be Granted (Dkt. No. 46) at ¶¶ 5-7 ("In order to begin clinical trials . . . the drug's sponsor must file an 'investigational new drug application' or 'IND' for approval to administer the drug to humans. Once an IND is approved, clinical trials may begin. . . . . The IND for use of CERA in patients . . . was filed in the United States on December 4, 2001.").

[45] *See* Gottfried Decl., Exh. H (identifying seven such trials in Boston and four in Springfield).

[46] *Id.* and 21 C.F.R. § 312.3(b).

[47] *See* Gottfried Decl., Exh. I.

collectively told this Court that they had filed "their" Biologic License Application ("BLA") for the PEG-EPO product.[48]

It is inconceivable that the PEG-EPO clinical trials in Massachusetts could have been initiated and conducted without contracts and substantial payments between the sponsor and the physicians in Massachusetts who recruited the patients for the studies and administered the PEG-EPO to those patients. These EPO-related activities in Massachusetts constitute substantial activity purposefully directed toward Massachusetts that is directly related to Amgen's cause of action here and renders Roche Switzerland subject to specific personal jurisdiction under the Federal Circuit test.[49]

C. The foreign Roche defendants are subject to general personal jurisdiction in Massachusetts

On a *prima facie* basis, the foreign Roche defendants have sufficient contacts with Massachusetts to justify this Court's exercise of general personal jurisdiction over them. In combination with their PEG-EPO-related activities in Massachusetts, the foreign Roche defendants' admitted presence in Massachusetts and their regular and systematic business contacts with Massachusetts companies substantially affect Massachusetts commerce, thus satisfying the requirement for general jurisdiction.

Defendants' motions to dismiss for lack of personal jurisdiction rest on their assertions that they do "not have substantial or 'continuous and systematic' contacts with Massachusetts."[50]

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[48] *See* Docket No. 51, the "Supplemental Declaration of Howard Suh, Esq. in Support of Defendants' Motion [sic: Motions] to Dismiss . . . ," which states "In Defendants' Memorandum in Support of their Motion To Dismiss, Defendants' [sic] informed the Court that ***their*** Biologics License Application ('BLA') for ***their*** product, CERA . . . , was expected to be filed with the U.S. Food and Drug Administration ('FDA') this month. . . . By this declaration, Defendants inform the Court that they have submitted ***their*** BLA to the FDA on April 19, 2006 . . . ." (emphases added).

[49] *3D Systems, Inc. v. Aarotech Labs., Inc.*, 160 F.3d 1373, 1378 (Fed. Cir. 1998).

[50] Roche Switzerland Memo at p. 3; Roche Germany Memo at p. 3.

The facts of record contradict these assertions.

1. Roche Switzerland

Roche Switzerland has continuous and systematic contacts with Massachusetts. On the last page its memorandum, Roche Switzerland reluctantly admits that during last year alone, 137 of its employees came to Massachusetts for the express business purpose of "evaluat[ing] potential technology for future licensing."[51] Roche Switzerland also admits that it has a "number of clinical trials sponsorships and licensing agreements with Massachusetts partners."[52] Because 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.

Roche Switzerland states unequivocally that "[n]o Massachusetts court has ever exercised jurisdiction over Roche Switzerland."[53] Yet Roche Switzerland was a defendant in a Massachusetts state court as recently as four years ago, in which the court found that Roche Switzerland and the other defendants were "doing business" in Massachusetts, and Roche Switzerland agreed not to have the court consider any challenge to personal jurisdiction.[54]

Thus, at the very least, Roche Switzerland has entered into contracts with Massachusetts entities (*e.g.*, doctors, clinics and hospitals) to engage in clinical trials where Massachusetts residents are subjected to Roche Switzerland's experimental drugs, and regularly sends hundreds of its employees into Massachusetts to evaluate business opportunities and to solicit and enter into licensing agreements and other contracts with Massachusetts companies (and presumably

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[51] Roche Switzerland Memo at p. 14.

[52] Roche Switzerland Memo at p. 4.

[53] Roche Switzerland Memo at p. 4.

[54] *Ciardi v. F. Hoffmann-La Roche, Ltd.*, 436 Mass. 53, 55, 762 N.E.2d 303, 306 (Mass. 2002) ("Several defendants also sought to dismiss the plaintiff's complaint for lack of personal jurisdiction . . . . These motions were not addressed by the judge pursuant to agreement by the parties. . . . The defendants, who dominate international markets for vitamin products, are foreign corporations doing business in the Commonwealth of Massachusetts.").

was and is exchanging payments with those companies). Roche Switzerland chose not to disclose the number and extent of those contacts with Massachusetts, but its vague admissions are enough to show that it has been "engaged in or soliciting business in the Commonwealth, permanently or temporarily," and its business activities "affect the commerce of Massachusetts substantially," rendering it subject to general personal jurisdiction in Massachusetts under Mass. Gen. Laws Ann., ch. 223, § 38.[55] Based on the public record and its admissions in its motion papers, Roche Switzerland's contacts with Massachusetts constitute the kind of "continuous and systematic" contacts sufficient to justify the exercise of general personal jurisdiction under Federal Due Process.

2. Roche Germany

Roche Germany has similarly been "engaged in or soliciting business in the Commonwealth, permanently or temporarily," and has the continuous and systematic business contacts with Massachusetts to justify general personal jurisdiction. Roche Germany and its declarant, Mr. Meisiek, admit that "Roche Germany currently maintains a limited number of contracts with partners in Massachusetts" that are "all either licensing or research and development agreements pertaining to diagnostics or pharmaceuticals."[56] Roche Germany describes its business connections with Massachusetts as amounting to "one unsubstantial physical contact," but admits that this "one contact" involves "intermittent visitation by various employees to the U.S., including Massachusetts . . . to evaluate potential licensing and research co-operations."[57]

Roche Germany states that it has "neither sued nor been sued in Massachusetts in over a

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[55] *Walsh v. National Seating Co., Inc.*, 411 F. Supp. 564, 574 and 575 (D. Mass. 1976).
[56] Meisiek Declaration (Docket No. 47) at ¶ 14; Roche Germany Memo at p. 4.
[57] Roche Germany Memo at p. 4.

decade."[58] But in the *Columbia University v. Roche Diagnostics GmbH* case,[59] a patent infringement case transferred to this Court from the Southern District of New York, Roche Germany appeared as the defendant and filed an Amended Answer in 2001 in which it admitted that it "is transacting business in this district."[60]

Just as has Roche Switzerland, Roche Germany has apparently been sending its employees into Massachusetts to solicit and enter into licensing and research-and-development contracts with Massachusetts companies. Indeed, Roche Germany admitted as recently as 2001 that it was transacting business in Massachusetts. Roche Germany has thus been "engaged in or soliciting business in the Commonwealth, permanently or temporarily," rendering it amenable to service of process under Mass. Gen. Laws. Ann., ch. 223, § 38, and its contacts with Massachusetts constitute the kind of continuous and systematic contacts sufficient to justify the exercise of general personal jurisdiction.[61]

D. The exercise of personal jurisdiction over the foreign Roche defendants would not be unreasonable or unfair

Amgen has made a *prima facie* showing of minimum contacts under the first two prongs of the Federal Circuit Due Process test. Therefore, to avoid jurisdiction, the foreign Roche defendants "must present a compelling case that the presence of some other considerations

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[58] Roche Germany Memo at p. 4.

[59] The Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH (formerly known as Boehringer Mannheim GmbH), Civ. No. 93-11512 NG (D. Mass.).

[60] *See* Gottfried Decl., Exh. J at ¶ 3.

[61] The foreign Roche defendants attempt a favorable contrast of their own contacts with Massachusetts against the defendant bank's contacts in *U.S. v. Swiss American Bank, Ltd.*, 274 F.3d 610 (1st Cir. 2001), in which the 1st Circuit affirmed this Court's denial of jurisdiction, asserting that "[t]his very Court has recently denied jurisdiction on such a motion where the defendant had far more contacts with the forum state than the instant defendant." Roche Germany Memo at p. 5; Roche Switzerland Memo at p. 5. But Defendants' characterization of the *Swiss American* defendant as having contacts "with the forum state" is somewhat misleading; in that case, this Court was not analyzing the defendant's contacts with Massachusetts or any other State; it was analyzing the defendant's contacts with the United States as a whole. *Swiss American*, 274 F.3d at 619-620.

would render jurisdiction unreasonable."[62] This they cannot do.

The constitutional reasonableness analysis involves the following factors: (1) the burden on the Roche defendants to litigate in this Court; (2) the interests of the people of Massachusetts in resolving this dispute; (3) Amgen's interest in obtaining relief; (4) the interstate judicial system's interest in obtaining the most efficient resolution of this controversy; and (5) the shared interest of the several States in furthering fundamental substantive social policies.[63]

This Court's exercise of jurisdiction over the foreign Roche defendants is reasonable and fair. First, because they are foreign companies, the burden on the foreign Roche defendants of litigating this action here is no more than if the action were litigated in any other District.[64] This factor does not weigh against exercising jurisdiction here.

Second, Massachusetts has an interest in having this action resolved here. The purpose of this declaratory judgment action is to determine whether the Defendants' imminent marketing, sale, and use of PEG-EPO will infringe Amgen's patents-in-suit. Massachusetts, just like any other state in which the Roche defendants will market and sell their PEG-EPO product, has an interest in preventing infringing activity. Moreover, although it is not a Massachusetts company, Amgen has a substantial presence in Massachusetts through its research facility in Cambridge.[65] Consequently, this factor is either neutral or slightly favors jurisdiction.

Third, Amgen has a distinct interest in obtaining convenient relief in this Court. This

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[62] *Akro Corp.*, 45 F.3d at 1546, quoting *Burger King*, 471 U.S. at 477; *Elecs. For Imaging*, 340 F.3d at 1350.

[63] *Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1363 (Fed. Cir. 2001). *See also Beverly Hills Fan*, 21 F.3d at 1568 (a defendant can defeat otherwise constitutional personal jurisdiction only in "the rare situation in which the plaintiff's interest and the state's interest in adjudicating the dispute in the forum are so attenuated that they are clearly outweighed by the burden of subjecting the defendant to litigation within the forum.").

[64] *See Pritzker v. Yari*, 42 F.3d 53, 62 (1st Cir. 1994) ("this factor is only meaningful where a party can demonstrate some kind of special or unusual burden").

[65] *See* Gottfried Decl., Exh. K.

Court is very familiar with Dr. Lin's inventions, the patents-in-suit, their claims, and their prosecution histories, and with some or all of the potential attacks on those patents that the Roche defendants may bring in this action. Consequently, litigating this action here is likely to be more streamlined and thus less expensive for Amgen. This factor favors jurisdiction.

Fourth, the interstate judicial system's interest in obtaining the most efficient resolution of this controversy is best satisfied in this Court, for much the same reasons as stated above for the third factor. The Roche defendants argue that this factor weighs against jurisdiction because Amgen "may still have its day in court against the U.S. Defendant, which does not dispute personal jurisdiction."[66] This argument misses the point. Given this Court's familiarity with the patents-in-suit and the technology involved, it will be more efficient for this Court to hear this action than it would be for any other District Court to do so, thus advancing the interstate judicial system's interest in the most efficient resolution. This factor thus favors exercising jurisdiction.

Fifth, litigating this action in this Court furthers "the shared interests of the several States in furthering fundamental substantive social policies."[67] The foreign Roche defendants argue that exercising jurisdiction over them will "have a chilling effect on future business dealings in the United States . . . by international businesses."[68] This argument is vacuous. Foreign companies that ship experimental drugs into the United States with the knowledge that they will be administered to residents of a given State should expect to be subject to the jurisdiction of the courts of that State. Every State has an interest in protecting its residents through its judicial system against the various harms that can result from the use of such foreign-made products, especially experimental drugs. This social policy far outweighs any hypothetical "chilling" effect

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[66] Roche Switzerland Memo at p. 11.

[67] *Burger King*, 417 U.S. at 477.

[68] Roche Switzerland Memo p. 12.

that might occur by subjecting the foreign Roche defendants to jurisdiction in this Court.

The foreign Roche defendants are both subject to service of process in Massachusetts, and the exercise of jurisdiction over them comports with the constitutional requirements of Due Process. Consequently, this Court should deny their motions to dismiss.

III. ALTERNATIVELY, AMGEN SHOULD BE GRANTED LEAVE TO TAKE JURISDICTIONAL DISCOVERY

In the First Circuit, a plaintiff confronted with a motion to dismiss for lack of personal jurisdiction will ordinarily be afforded the opportunity to conduct jurisdictional discovery.[69] As the First Circuit has said, "[w]hen the fish is identified, and the question is whether it is in the pond, we know no reason to deny a plaintiff the customary license."[70]

A. The current record establishes at least a colorable case that the foreign Roche defendants are subject to personal jurisdiction

As discussed above, Amgen has identified evidence in the public domain and the Defendants have admitted facts in their motion papers that collectively establish more than a colorable case that the foreign Roche defendants are subject to specific and/or general personal jurisdiction in this Court. Amgen is thus entitled to jurisdictional discovery.[71] Consequently, if the Court believes that the facts of record are insufficient to deny the motions to dismiss, Amgen should be granted leave to take jurisdictional discovery to create a complete factual record on

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[69] *See U.S. v. Swiss American Bank, Ltd.*, 191 F.3d 30, 45-46 (1st Cir. 1999) ("A timely and properly supported request for jurisdictional discovery merits solicitous attention."); *U.S. v. Swiss American Bank, Ltd.*, 274 F.3d 610, 625 (1st Cir. 2001) ("We have long held that 'a diligent plaintiff who sues an out-of-state corporation and who makes out a colorable case for the existence of *in personam* jurisdiction *may* well be entitled to a modicum of jurisdictional discovery if the corporation interposes a jurisdictional defense.'") (quoting *Sunview Condominium Ass'n v. Flexel Int'l, Ltd.*, 116 F.3d 962, 964 (1st Cir. 1997)); *Boit v. Gar-Tec Prods., Inc.*, 967 F.2d 671, 680-81 (1st Cir. 1992) ("The Boits underestimate their own ability and burden to create a record that supports their jurisdictional allegations. The Boits could have requested that the court allow discovery on the limited issue of personal jurisdiction. . . . it might have been an abuse of discretion to deny the request.").

[70] *Surpitski v. Hughes-Keenan Corp.*, 362 F.2d 254, 255-256 (1st Cir. 1966).

[71] *U.S. v. Swiss American Bank, Ltd.*, 274 F.3d at 625.

which this Court may consider Defendants' motions to dismiss.

B. Limited jurisdictional discovery is justified by the questions raised (but not answered) in the foreign Roche defendants' motion papers

As discussed above, the foreign Roche defendants admit that they conduct clinical trials in Massachusetts, that they solicit and enter into licensing and research-and-development contracts with Massachusetts companies, and that hundreds of their employees regularly come to Massachusetts. But they do not disclose the nature or number of these contacts (*e.g.*, just what these employees do in Massachusetts, how long they stay, how many companies they deal with, and the nature and number of deals that have been negotiated or consummated). They say they have no control over where their PEG-EPO goes or is used in the United States. But they do not address the relevant question of what they knew or believed about where their PEG-EPO product is transported or is being used. They assert a lack of connection between the Roche companies.[72] But it is entirely unclear whether Roche US is acting as an agent for either foreign Roche defendant. Amgen should be permitted to pursue the answers to these questions through limited jurisdictional discovery. For example, the regulatory documents that have already been submitted by the Defendants (*e.g.*, the IND and BLA documents) will reveal the identity of the license-holder(s), the sponsors of the clinical trials, and the role of each Defendant in the manufacture, importation, use and sale of their PEG-EPO product.

Simply put, the foreign Roche defendants' motion papers raise more questions about their contacts with Massachusetts than they answer. Amgen should be permitted limited discovery to fill in the gaps in the factual record.

C. The requested discovery

In order to investigate the nature and extent of the foreign Roche defendants' contacts

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[72] Roche Switzerland Memo at p. 8-9; Roche Germany Memo at p. 8-9.

with Massachusetts and the United States as a whole,[73] Amgen seeks limited discovery from the Defendants regarding the following subjects:

- The nature and number of the foreign Roche defendants' contacts with Massachusetts residents and companies (including but not limited to the sponsorship and conduct of clinical trials);
- The nature and extent of each Defendants' involvement in and awareness of the importation and use of their PEG-EPO product in the U.S. and in Massachusetts in particular;
- Statements by Defendants in regulatory filings seeking approval to market their PEG-EPO product (including but not limited to the Defendants' IND submissions filed on December 4, 2001 and March 17, 2003, and their BLA filed on April 19, 2006) relating to their involvement in manufacturing, importation, distribution and use of PEG-EPO in Massachusetts and the U.S.;
- Defendants' solicitation of and entry into contractual relationships with Massachusetts entities (including but not limited to Genetics Institute and Fresenius Medical Care);
- The relationship of each Defendant within the worldwide Roche Group business organization as that relationship concerns Roche business activities in the U.S.;
- The financial arrangements among Defendants regarding any anticipated or actual revenues and/or profits from their activities in Massachusetts;
- Lawsuits in which Defendants have been asserted by any party to be subject to the jurisdiction of Massachusetts courts; and
- The foreign Roche defendants' contacts with the U.S. as a whole.

The proposed order submitted herewith sets out a schedule for completing this jurisdictional discovery within 75 days from the Court's ruling on Amgen's instant request.

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[73] In federal question cases such as this, if a defendant lacks sufficient contacts with a single state to meet any state's long-arm statute, Fed. R. Civ. P. 4(k)(2) allows a court to rely upon the defendant's contacts with the United States as a whole. *See U.S. v. Swiss American Bank, Ltd.*, 116 F. Supp. 2d 217, 220 (D. Mass. 2000). The foreign Roche defendants have said nothing about their amenability to personal jurisdiction under the long-arm statute of any state other than Massachusetts, or their other contacts in the United States (save for their admitted dealings with Roche US). Amgen should be allowed discovery to pursue these facts.

IV. CONCLUSION

For the foregoing reasons, Amgen respectfully requests that this Court (1) deny the foreign Roche defendants' motions to dismiss for lack of personal jurisdiction; or alternatively (2) enter the proposed Order submitted herewith granting Amgen leave to take jurisdictional discovery and thereafter file a supplemental opposition to those motions.

April 25, 2006

Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned counsel for Plaintiff Amgen Inc. hereby certifies that this document filed through the ECF System will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on the above date.

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