IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

DEFENDANTS' BENCH MEMORANDUM REGARDING THE RELEVANCE OF BARON AND GOLDWASSER'S PRIOR ART AND REFUTING AMGEN'S ASSERTIONS THAT THE BARON-GOLDWASSER IND AND GOLDWASSER GRANTS ARE NOT "PRINTED PUBLICATIONS," ANTICIPATORY OR ENABLING UNDER 35 U.S.C. § 102

Amgen's attack on three prior art documents: the Baron-Goldwasser IND application and the two Goldwasser NIH grant applications, already admitted into evidence *without objection* as TRX 2004, TRX 2043, and TRX 2045, is erroneous for at least the following reasons:

(i) TRX 2004, 2043 and 2045 are prior art relating in part to the Baron-Goldwasser clinical study that has already been determined to be prior art by this Court and the Federal Circuit.[1]

(ii) TRX 2004, 2043 and 2045 are "printed publications" within the meaning of 35 U.S.C. § 102 and their relevance is in no way diminished by the fact that the data generated from the prior art Baron-Goldwasser clinical study was not submitted to a scientific journal for publication.

(iii) In addition to being "printed publications" each of these documents provides irrefutable evidence of prior public use under 35 U.S.C. § 102.

[1] *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 111 (D. Mass. 2001); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003). Confirming the prior art status, on September 11, 2007 the Court granted Roche's motion in limine to preclude Amgen from arguing otherwise in this case. (D.I. 1028). "The Goldwasser study is prior art . . . I've prior held and been upheld. Prior art." Trial Tr. 579:3-5.

(iv) In addition to being anticipatory prior art publications, these documents are evidence of derivation under 35 U.S.C. § 102 (f), prior inventorship under 35 U.S.C. § 102 (g), and obviousness under 35 U.S.C. § 103.

I. The IND and Grant Applications are prior art under 35 U.S.C. §§ 102(a) and (b)

35 U.S.C. § 102(a) states:

> A person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

35 U.S.C. § 102(b) states:

> A person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

The Baron-Goldwasser IND application (TRX 2004, attached as Ex. 1) submitted March 2, 1979 and the Goldwasser NIH grant applications (TRX 2043, attached as Ex. 2) (TRX 2045, attached as Ex. 3) dated April 8, 1982 and August 31, 1984, all predate Amgen's November 30, 1984 invention date[2] and are "printed publications" within the meaning of § 102.[3]

A. "Printed Publication"

The Goldwasser NIH grant applications are clearly prior art. Grant proposals and grant applications, such as those submitted to the National Science Foundation and the National Institutes of Health are printed publications under Section 102. *E.I. Du Pont de Nemours & Co. v. Cetus Corp.*, 1990 Dist. LEXIS 18382, *6-*8 (N.D. Cal. 1990) (unreported). Additionally, publicly accessible submissions to government entities constitute printed publication prior art.

[2] Amgen argues an earlier date for the claimed "pharmaceutical compositions" but Roche disputes that date because disclosure regarding dosing, adjuvant/carriers/diluents, and therapeutic effects was not included until the application filed September 28, 1984. Since the patent does not disclose any material suitable for administration to patients, at best, September 28, 1984 is the earliest date that the claims drawn to pharmaceutical compositions are entitled.

[3] During a sidebar conference, the Court raised questions about what constitutes a "printed publication" within the meaning of 35 U.S.C. § 102. (Trial Tr. 814) While TRX 2004, 2043 and 2045 are clearly evidence of "use by others" and "public use" under 35 U.S.C. § §102 (a) and (b) respectively, to assist the Court, this submission expands on the law of printed publications, previously explained in Roche's prior submission (D.I. 1075).

See Amer. Stock Exchange, LLC v. Mopex, Inc., 250 F. Supp. 2d 323, 329-30 (S.D.N.Y. 2003) (finding World Equity Benchmarks Application submitted to the SEC to be prior art). In addition, testimony from Dr. Goldwasser and evidence adduced in this case suggested that he showed his draft proposals to Amgen before he had any written agreement with them and before submitting the applications to the NIH. (*See* TRX 2044, attached as Ex. 4; Trial Tr. at 561:1-564:1.)

A reference is a "printed publication" if it was "'available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, [could] locate it.'" *Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006), quoting *In re Wyer*, 655 F.2d 221, 226 (C.C.P.A. 1981).[4] "The 'printed publication' provision of § 102(b) 'was designed to prevent withdrawal by an inventor . . . of that which was already in the possession of the public.'" *Bruckelmyer*, 445 F.3d at 1378, quoting *In re Wyer*, 655 F.2d at 226. Thus, "[w]hether a given reference is a 'printed publication' depends on whether it was 'publicly accessible' during the prior period." *Bruckelmyer*, 445 F.3d at 1378, citing *In re Wyer*, 655 F.2d at 226.

"Accessibility goes to the issue of whether interested members of the relevant public could obtain the information if they wanted to. If accessibility is proved, there is no requirement to show that particular members of the public actually received the information." *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988). In *Bruckelmyer*, the Federal Circuit held that a Canadian patent application and the figures associated with it were 'publicly accessible' and thus a 'printed publication' under 35 U.S.C. § 102(b). *Bruckelmyer*, 445 F.3d at 1378 (application only available for viewing at Quebec patent office). Public

[4] "Reasonable diligence" does not mean nominal effort. "The need to flip through hundreds of documents, although time-consuming, clearly falls within the bounds of 'reasonable diligence.'" *Amer. Stock Exchange, LLC v. Mopex, Inc.*, 250 F. Supp. 2d 323, 329 (S.D.N.Y. 2003).

accessibility for printed publications does not require wide dissemination. *See Mazzari v. Rogan*, 323 F.3d 1000, 1005-06 (Fed. Cir. 2003) (German language reference available in Germany was prior art under § 102); *E.I. DuPont de Nemours & Co. v. Cetus Corp.*, 1990 U.S. Dist. LEXIS 18382, *4 (N.D. Cal. Dec. 11, 1990) (unreported) ("Publication does not require dissemination in books or journals."); *Massachusetts Inst. of Tech. v. AB Fortia*, 774 F.2d 1104, 1109 (Fed. Cir. 1985) (where existence of reference was made known to 50 to 500 persons of ordinary skill, with actual reference disseminated to 6 people, reference was prior art under § 102); *In re Hall*, 781 F.2d 897, 900 (Fed. Cir. 1986) (thesis that was cataloged in one library was prior art under § 102).

Here the evidence establishes that the Baron-Goldwasser IND and the Goldwasser NIH grant applications are publicly accessible prior art. Once filed with their respective agencies, NIH grants and IND applications are available upon request from the Department of Health and Human Services and Food and Drug Administration respectively under the Freedom of Information Act (FOIA). In fact, in this case, Roche's counsel obtained the Goldwasser Grant through a FOIA request, as evidenced by documents produced ***by Amgen***. (*See* FOIA Correspondence, AM-ITC 00040201-07, attached as Ex. 5). Similarly, Amgen's production shows that a FOIA request was exactly how a copy of the Baron-Goldwasser IND was obtained from the government in the first place. (*See* TRX 2004, Ex. 1 at AM-ITC 01006756, August 23, 2000 Castle letter to Safir). While these requests occurred more recently, these documents were equally accessible through FOIA requests in 1983-84. *See, Cetus*, 1990 U.S. Dist. LEXIS 18382 at *8 ("Access to the NIH Grant Application prior to March 28, 1984 was available under the Freedom of Information Act pursuant to 45 C.F.R. 5.72(b), which provides that records pertaining to Department of Health and Human Services grant applications are available to the

public under the Act."). Since 1976, there have been no amendments to FOIA that would have altered the availability of documents since 2000 as compared to 1983-1984.[5]

Today and in the relevant time period, the presumption under FOIA is complete disclosure. In instances in which any material is withheld, FOIA provides "that an agency has the burden of proving that withheld material falls within a FOIA exemption." *Orion Research Inc. v. Env't Prot. Agency,* 615 F.2d 551, 553 (1st Cir. 1980). Amgen's arguments that "Federal Rules prevented the FDA from disclosing even the existence of the IND" are entirely without merit. Amgen cannot show that in 1983-84, a FOIA request for an NIH grant application or IND would have been categorically denied.[6]

Beyond availability through FOIA, Amgen's own documents show the Baron-Goldwasser IND and Goldwasser NIH grant applications were public knowledge to at least Amgen employees -- i.e., third parties -- and thus sufficiently "public" under §§ 102(a) and (b). *See Baxter Int'l, Inc. v. Cobe Labs, Inc.*, 88 F.3d 1054, 1058-59 (Fed. Cir. 1996) (art "was in public use" under § 102(b) when disclosed to a select few in a laboratory). For example, in a memorandum dated September 17, 1984 from D. Vapnek to J. Fenno and N. Stebbing, with G.B. Rathmann, F.K. Lin, and J. Egrie cced (TRX PVF, attached as Ex. 6), the Baron Goldwasser IND is appended. A December 3, 1984 Memorandum from Joan Egrie and Jim Fenno distributed to seventeen (17) Amgen employees (TRX OSR, attached as Ex. 7, at AM-ITC 00554403), discusses the results of "Dr. Goldwasser's first EPO trial." Similarly, in a July 24,

[5] Since the passage of FOIA in 1966, there have been five amendments: in 1974, 1976, 1986, 1996, and 2002. *See* "FOIA Legislative History," available at http://www.gwu.edu/~nsarchiv/nsa/foialeghistory/legistfoia.htm.

[6] Even if certain material within a request is exempt, the law is clear that "an agency cannot justify withholding an entire document simply by showing that it contains some exempt material." *Public Citizen Health Research Group v. Food & Drug Admin.*, 185 F.3d 898, 907 (C.A.D.C. 1999). The solution is often as simple as redacting exempt information. *See, e.g., In re Eli Lilly & Co., Prozac Prods. Liability Litig.*, 142 F.R.D. 454, 457 (S.D. Ind. 1992) ("[T]he FDA will delete reporters' names from 'adverse reaction reports, product experience reports, consumer complaints, and other similar data' before making IND's and NDA's available for public disclosure under the Freedom of Information Act, 5 U.S.C. § 552.")

1984 letter (TRX 2044, Ex. 4), Dr. Vapnek directs Goldwasser as to what to include and exclude on his NIH grant applications - indicative that ***at least*** Mr. Vapnek had knowledge of the contents of the applications at issue.

For all of the reasons explained above, TRX 2004, 2043, and 2045 not only constitute "printed publications" but further constitute evidence of prior public use of the invention under 35 U.S.C. § 102. Even if, contrary to the evidence here, the documents are not considered to constitute prior art publications, they are indisputably evidence from which one could infer that the therapeutic use of a pharmaceutical composition of EPO was in public use within the meaning of §§ 102(a) and (b) prior to the critical date. *See In re Epstein*, 32 F.3d 1559, 1567 (Fed. Cir. 1994) (holding that facts set forth in and inferred from non-prior art subsequently published abstracts supported legal conclusion that products at issue were in public use under § 102).[7]

II. The IND and Grant Applications are Relevant Prior Art

Amgen implies that the investigators' purported "failure to publish" the results of the prior art Baron Goldwasser clinical study somehow calls into question whether the Baron Goldwasser IND or Goldwasser grants disclose every claim element or are enabling. Amgen's implication does not withstand scrutiny. The Federal Circuit has already determined that "If the claim term 'therapeutically effective' encompasses the patient responses described in the specification, as it appears to us it does, then the Goldwasser study may constitute invalidating prior art under § 102(a) or § 103 even if he did not achieve his intended result." *Amgen, Inc v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003) (emphasis added).

[7] Furthermore, the patients and doctors involved in the Baron-Goldwasser study were not bound by any confidentiality agreement, and the experiments were conducted in public hospitals subject to observation by hospital staff as well. See *Baxter*, 88 F.3d at 1059 (laboratory was located in a public building where third parties, including co-workers observed prior art in use).

Claim 1 of the '422 patent reads as follows:

> A pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant or carrier, wherein said erythropoietin is purified from mammalian cells grown in culture.

As explained by Dr. Spinowitz, TRX 2004 discloses a pharmaceutical composition containing human erythropoietin derived from mammalian kidney cells and a pharmaceutically acceptable diluent, human serum albumin. (*See, e.g.*, Trial Tr. at 706:6-708:2, 708:10-25) That pharmaceutical composition, when administered to patients was therapeutically effective. (*See, e.g.*, Trial Tr. at 709:6-22, 711:1-712:12) Similarly, the Goldwasser Grant Application, TRX 2045, discloses every claim element. (*See* TRX 2045, Ex. 3 at AM670206397) These references constitute anticipatory prior art and it is Amgen's burden to show that the references are not enabling. *See* 314 F.3d at 1355, 1355 n.22. ("We hold that an accused infringer should be similarly entitled to have the district court presume the enablement of unclaimed (and claimed) material in a prior art patent defendant asserts against a plaintiff . . . We note that by logical extension, our reasoning here might also apply to prior art publications as well.").[8] Given the overwhelming evidence demonstrating that the Baron-Goldwasser study was "therapeutically effective" as defined by the Federal Circuit, Amgen fails to provide any explanation as to why TRX 2004 or TRX 2045 are not enabling, let alone meet their burden of showing non-enablement by a preponderance of the evidence.

Moreover at minimum, each of TRX 2004, 2043 and 2045 renders claim 1 of the '422 patent obvious to one of skill in the art under § 103. For purposes of an obviousness inquiry,

[8] "The standard for enablement of a prior art reference for purposes of anticipation under section 102 differs from the enablement standard under 35 U.S.C. § 112 . . . While section 112 provides that the specification must enable one skilled in the art to use the invention, . . . section 102 makes no such requirement as to an anticipatory disclosure . . . [A]nticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabled to one of skill in the art." *Novo Nordisk Pharms, Inc. v. Bio-Technology Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005).

Amgen's enablement attack is irrelevant. *Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1578, 19 USPQ2d 1241, 1247 (Fed. Cir. 1991) ("While a reference must enable someone to practice the invention in order to anticipate under § 102(b), a non-enabling reference may qualify as prior art for the purpose of determining obviousness under § 103."). *See* 314 F.3d at 1357; *Pfund v. U.S.*, 40 Fed. Cl. 313, 348 (Fed. Cl. 1998). Accordingly, each of these exhibits are properly admissible and relevant.

III. The Goldwasser Baron IND and Goldwasser Grants are Evidence of Derivation Under 35 U.S.C. § 102(f)

35 U.S.C. § 102(f) states:

> A person shall be entitled to a patent unless he did not himself invent the subject matter sought to be patented.

Under this subsection, a person cannot patent an invention derived from another's invention. Derivation under § 102(f) requires demonstration of both "(1) prior conception of the invention by another and (2) communication of that conception to the patentee that is 'sufficient to enable [him] to construct and successfully operate the invention.'" *Int'l Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1376 (Fed. Cir. 2004).

Prior conception of the subject matter of '422 claim 1 is shown in the Baron-Goldwasser IND through manufacturing information detailing how to make the pharmaceutical composition and protocol for administering the drug (TRX 2004, Ex. 1 at AM-ITC 01006660-661, AM-ITC 01006663-67). Dr. Goldwasser's Grant Application describes a "Clinical test of epo," concluding "[the studies] show that epo can have a physiological effect in this type of anemia. We plan to continue these studies, but not as a part of this proposal." (TRX 2045, Ex. 3 at AM-ITC 00991064, (Grant Proposal of Dr. Goldwasser dated August 31, 1984); *see also* TRX 2043, Ex. 2 (Grant Proposal of Dr. Goldwasser, dated April 8, 1982) "Preliminary experiments, indicate that epo may well be useful in renal disease patients."). The Amgen communications

cited above (*see* TRX PVF (Ex. 6), TRX OSR (Ex. 7), and TRX 2044 (Ex.4)) confirm that this conception was communicated to Amgen and, thus, are highly relevant and properly admissible evidence.

Even if, contrary to the evidence here, the Baron-Goldwasser documents were not considered to be evidence of conception and communication of the entire invention claimed by '422 claim 1, these documents are still relevant in an obviousness inquiry. The Federal Circuit has held that "subject matter derived from another not only is itself unpatentable to the party who derived it under §102(f), but, when combined with other prior art, may make a resulting obvious invention unpatentable to that party under a combination of §§ 102(f) and 103." *Oddzon Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1403-04 (Fed. Cir. 1997). The Court noted that under § 102(f) "an invention . . . may not be unpatentable to a third party who did not receive the disclosure . . . but is [to someone who did]." *Id.* at 1403. Thus, under § 102(f), if a patent applicant receives secret, non-public information from a non-inventor, it can still be used against them in a § 103 obviousness challenge. Even if the documents at issue were not "public," (which they clearly were) they still qualify as prior art under § 102(f) and are properly available evidence relevant to Roche's § 102(f)/§ 103 obviousness defense.

IV. The Goldwasser Baron IND and Goldwasser Grants are Evidence of Prior Invention Under 35 U.S.C. § 102(g)

35 U.S.C. § 102(g)(2) states:

> A person shall be entitled to a patent unless before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it.

In other words, if someone else invented first, a later applicant cannot patent the same invention, regardless of whether or not the first inventor tried to acquire a patent or not. Section 102(g)(2), like § 102(f), does not require knowledge or use of a prior invention or public

accessibility at the time the patented invention was made. *See Int'l Glass Co. v. United States*, 408 F.2d 395, 402 (Ct. Cl. 1969); *see also E.I. Du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1437 (Fed. Cir. 1988) ("Nor does § 102(g) contain a 'known to the art' requirement apart from the requirement of no abandonment, suppression or concealment"). In *E.I. Du Pont*, the Federal Circuit made clear "that certain prior work at issue, solely because it satisfied § 102(g) (i.e. it was reduced to practice and had not been abandoned, suppressed or concealed), could be used for § 103 purposes." *Id.* The court acknowledged that such art, akin to prior art under § 102(e), was not known to the public but still prior art. *Id.* Accordingly, under § 102(g), public accessibility is not a requirement for admission and evidence offered pursuant to this subsection can properly be considered prior art regardless of whether or not it was "public."

Amgen argues that Drs. Baron and Goldwasser's failure to publish their study somehow demonstrates that they did not conceive the therapeutic use of human EPO or alternatively had abandoned, suppressed or concealed the invention described in their IND and grant application. As discussed above, the Baron-Goldwasser IND and the Goldwasser Grant Applications provide clear evidence of prior conception as well as contemporaneous recognition and appreciation.[9] The fact that data from the clinical study was not published is simply irrelevant to this inquiry.

Amgen has no basis for its contention that by failing to publish the study in a scientific journal, the Baron-Goldwasser study was abandoned, suppressed or concealed under § 102(g). The Federal Circuit has recognized two types of conduct that fit into 102(g)'s exception: (1) active concealment of an invention, and (2) unreasonable delay in making the invention known. *Eolas Tech Inc. v. Microsoft Corp.*, 399 F.3d 1325, 1333 (Fed. Cir. 2005).

[9] The fact of filing the IND alone shows contemporaneous recognition.

Plainly there was no active concealment. As discussed above, the IND and NIH grant applications were publicly available at least to third-party Amgen (as well as other interested third parties). In addition, the doctors and patients were not bound by any confidentiality agreement and all testing was done publicly within the view of other third parties.

Moreover, under § 102(g) any delay of public disclosure is excused if the inventor is refining, perfecting, or improving the invention. *Id*. at 1333 (citing *Lutzker v. Plet*, 843 F.2d 1364, 1367 (Fed. Cir. 1988)) ("An inference of suppression or concealment may be overcome with evidence that the reason for the delay was to perfect the invention.") In correspondence to the NIH and FDA, Drs. Baron and Goldwasser repeatedly indicated their intent to continue their studies as more urinary EPO became available for testing. (*See* TRX 2043, Ex. 2 at AM-ITC 00927021, AM-ITC 00927025 (Goldwasser Grant Application dated April 8, 1982); TRX 2045, Ex. 3 at AM-ITC 00991064 (Goldwasser Grant Application dated August 31, 1984); TRX 2050, attached as Ex. 8 at BARON 00042, 00046 (Dr. Baron Physician Sponsored IND); TRX 2004, Ex. 1 at AM-ITC 01006619, AM-ITC 01006621, AM-ITC 01006627 (Dr. Baron IND)).

In his 1982 NIH application, Goldwasser explains his goal to accumulate "enough pure epo to do a significant clinical trial . . . When enough material is at hand we will continue these trials...." (TRX 2043, Ex. 2 at AM-ITC 00927025 (Goldwasser Grant Application)). Likewise, Dr. Baron wrote the FDA twice, in 1985 and 1987, stating his wish to continue his work, but "follow-up studies have been delayed because of lack of availability of sufficient amounts of purified human urinary erythropoietin to permit us to carry out the investigations" and further expressing his hope to start within "the next several months...to continue studies undertaken." (TRX 2004, Ex. 1 at AM-ITC 01006621 (October 2, 1985 letter to Department of Health and Human Services); *see also* TRX 2004, Ex. 1 at AM-ITC 01006619 (February 11, 1987 letter to

Department of Health and Human Services)). Thus, both Drs. Goldwasser and Baron made clear that they were in the midst of further testing.

Not until 1988 -- years after the filing of the Lin specification -- did Dr. Baron request that his IND "be put on inactive status," yet expressly reserved " the opportunity to re-open this study by submission of a protocol amendment with proposed investigational plan for the coming year." (TRX 2004, Ex. 1 at AM-ITC 01006614 (June 16, 1988 Baron letter to Department of Health and Human Services)) Accordingly, the study was not abandoned, was actively practiced prior to Lin's November 30, 1984 filing date, and any purported delay of disclosure argued by Amgen (despite the study's public status) is excused because Drs. Baron and Goldwasser were still refining or perfecting their invention through additional testing.

Accordingly, the documents at issue are prior art under § 102(g), regardless of whether they are "public" or were widely disseminated, because they independently demonstrate conception of the invention at issue and the evidence clearly refutes any assertion that the pharmaceutical composition was abandoned.

V. Conclusion

For the above reasons, as a matter of law and fact, the already-admitted Baron-Goldwasser IND and Goldwasser NIH applications (TRX 2004, 2043, 2045) qualify as prior art -- both as "printed publications" under §§ 102(a) and (b), and as evidence of derivation and prior invention under 35 U.S.C. §§ 102(f) and (g) respectively. Likewise, TRX PVF, TRX OSR, TRX 2044, TRX 2050 and AM-ITC 00040201-207 are relevant and properly admissible evidence under controlling legal precedent relating to §102(f).

Dated: September 20, 2007
Boston, Massachusetts

Respectfully submitted,
F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE INC.

By its attorneys,

/s/ Thomas F. Fleming

Leora Ben-Ami (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000

Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292
ktoms@bromsun.com

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/s/ *Thomas F. Fleming*
Thomas F. Fleming