UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LAROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN LAROCHE INC., a New Jersey Corporation, Defendants.	Civil Action No.: 05-12237 WGY

AMGEN'S RESPONSE TO ROCHE'S LISTS OF PRIOR ART AND CHART IDENTIFYING CLAIMS BY CATEGORY REQUESTED BY THE COURT AT THE OCTOBER 4, 2007 AFTERNOON HEARING

Pursuant to the Court's October 4, 2007 request, Amgen hereby submits its report as to the list of exhibits claimed to anticipate and the list of exhibits which allegedly constitute prior art as well as the identification of the claims in suit which are product, process, vs. product by process claims.

I. CATEGORIZATION OF THE CLAIMS IN SUIT AS PRODUCT, PROCESS, OR PRODUCT BY PROCESS CLAIMS

As the following table prepared by Roche reflects, the parties are in agreement:

CLAIM CHART

	Product	Process	Product by Process
'868		1 and 2	
'698		6-9	
'349		7	
'933	9, 12 (each depending from product by process claims)	11 and 14 (each depending from product by process claims)	3, 7, 8
'422	1		

II. LIST REGARDING THE EXHIBITS CLAIMED TO ANTICIPATE

As the annotated list set forth below regarding the exhibits claimed to anticipate reflects, the parties were unable to come to agreement. All of the exhibits proffered by Roche suffer from the fundamental defect that they fail to describe all of the limitations of the claims in suit, especially the source limitations. Various of the exhibits came into existence after the claimed inventions (*see, e.g.*, TRX 20, 2012, 164, 2054, 2060, 2068, 2079, 2084, and 2090) and are therefore not prior art. Various of the exhibits are based on the claimed inventions themselves (*see, e.g.*, TRX 2054, 2060, 2068, and 2079) and thus it would be inappropriate to consider them prior art. Various exhibits are unpublished, non-public documents pertaining to an experiment that Roche has failed to prove was not abandoned, suppressed, or concealed (*see, e.g.*, TRX 8, 9, 19, 2004, 2043, 2045, 2049, 2049A, 2050, and 2088). Various exhibits were never disclosed under 35 U.S.C. § 282 (*see, e.g.*, TRX 2051, 2054, 2084, and 2090). And, various exhibits are redundant of one another (*see, e.g.*, 8, 9, 19, 2004, 2043, 2045, 2049, 2049A, 2054, and 2088; 2050, 2051, and 2052; 2060, 2068, and 2079).

TRX	DESCRIPTION	Reasons for Removal from List
0008	~~Letter from Baron to Temple (FDA) Enclosing Materials for a Physician Sponsored IND for Human EPO~~	1. TRX 0008 is an unpublished, non-public document pertaining to an experiment that Roche has failed to prove was not abandoned, suppressed, or concealed. 2. TRX 0008 fails to meet all limitations of any asserted claim in suit. For example, as to the '933 claims, TRX 0008 fails to describe the recited "non-naturally occurring glycoprotein product." It fails to describe a product that has been expressed by a non-human mammalian cell, and more specifically a CHO cell. It fails to meet still other limitations. 3. Assuming either TRX 0009 or TRX 2050 were to be presented to the jury — which they should not — TRX 0008 is redundant and cumulative of those exhibits and therefore should not be presented.
0009	~~Letter from Baron to Temple (FDA) Enclosing Materials for a Physician Sponsored IND for Human EPO~~	1. See reasons for removal re TRX 0008, above.
0019	~~Summary Sheet of Patient Data for all Three Patients~~	2. See reasons for removal re TRX 0008, above.
0020	~~Eschbach et al., "Correction of the Anemia of End-Stage Renal Disease with Recombinant Human Erythropoietin," New England Journal of Medicine, 316:73-78 (Jan. 8, 1987)~~	1. This reference came into existence after the date of Dr. Lin's inventions and therefore does not meet the Court's criterion as *prior* art (See 10/4/07 Trial Tr. 152:3-7: "Then I want a list of all exhibits which constitute prior art in this case, all the trial exhibits which constitute prior art. Now, there may be a bunch of exhibits that bear on the state of the knowledge, but they're not prior art. Prior art has to be prior.) 2. Given Roche's failure to specify precisely what in this reference purportedly anticipates precisely which claims in suit, Amgen objects to Roche's characterization of this exhibit as anticipatory prior art.
2002	~~Miyake et al, "Purification of Human Erythropoietin", J. Biol. Chem. 252(15):5558-64 (1977)~~	1. TRX 2002 fails to meet all limitations of any asserted claim in suit. For example, as to the '933 claims, TRX 2002 fails to describe the recited "non-naturally occurring glycoprotein product." TRX 2002 also fails to describe a product that has been expressed by a non-human mammalian cell, and more specifically a CHO cell. It fails to meet still other limitations. 2. Given Roche's failure to specify precisely what in this reference purportedly anticipates precisely which claims in suit, Amgen objects to Roche's characterization of this exhibit as anticipatory prior art.
2004	~~IND/NDA Subsequent Submissions Review Transmittal to M. Peterson from J. Baron (IND submitted 3/2/79)~~	1. See reasons for removal re TRX 0008, above.

TRX	DESCRIPTION	Reasons for Removal from List
2012. 164	~~Jacobs (1985) Isolation and Characterization of Genomic and cDNA Clones of Human Erythropoietin [at AM-ITC 000164 — 000168]~~	1. This reference came into existence after the date of Dr. Lin's inventions and therefore does not meet the Court's criterion as *prior* art (See 10/4/07 Trial Tr. 152:3-7.) 2. Given Roche's failure to specify precisely what in this reference purportedly anticipates precisely which claims in suit, Amgen objects to Roche's characterization of this exhibit as anticipatory prior art. 3. To the extent that Roche asserts that the claimed inventions are somehow anticipated by an alleged discussion of the cloning and expression of the human EPO gene in TRX 2012, since it is indisputable that Dr. Lin cloned the human EPO gene in October 1983, and achieved the expression of *in vivo* biologically active human EPO by March 1984, TRX 2012 is not prior art.
2043	~~Grant Application: Re: Erythropoietin, Purification, Properties, Biogenesis~~	1. See reasons for removal re TRX 0008, above.
2045	~~Grant Application: Erythropoietin: Purification, Properties, Biogenesis~~	1. See reasons for removal re TRX 0008, above.
2049	~~Documents from Dr. Baron~~	1. See reasons for removal re TRX 0008, above.
2049 A	~~Patient Horizontal Graphs for all 3 patients~~	1. See reasons for removal re TRX 0008, above.
2050	~~Clinical Study of Purified Human Erythropoietin (1979-1980)~~	1. See reasons for removal re TRX 0008, above.
2051	~~Essers, U., et al., "Effect of Erythropoietin in healthy subjects and in patients with chronic uremia" Klin. Wschr., 1973, 51:1005-1009 with certified translation~~	1. TRX 2051 fails to meet all limitations of any asserted claim in suit. For example, as to the '933 claims, TRX 2051 fails to describe the recited "non-naturally occurring glycoprotein product." It pertains to transfusion of a whole blood product — plasma. Notably, the specification to Dr Lin's patents expressly distinguishes his inventions away from transfusions and transfusion therapy. TRX 2051 also fails to describe a product that has been expressed by a non-human mammalian cell, and more specifically a CHO cell. And, since it is undisputed that plasma contains many components other than EPO, Roche failed to prove that any purported effect of the preparation was in fact caused by any EPO allegedly present in the plasma. TRX 2051 fails to meet still other limitations. 2. Roche failed to disclose TRX 2051 pursuant to 35 U.S.C. § 282.
2052	~~Esser et at, "Weitere Untersuchugen zur Wirksamkeit~~	1. See reason #1 for removal re TRX 2051, above.

TRX	DESCRIPTION	Reasons for Removal from List
	~~von Erythropoetin bei Patienten mit Nierensuffzienz," 1614-1624 (1974)~~	
2053	~~Essers et al, "Effect of Erythropoietin in Normal Men and in Patients with Renal insufficiency" European Dial. and Trans . Proceedings 2:398-402 (1975)~~	1. See reason #1 for removal re TRX 2051, above. 2. Assuming either TRX 2051 or TRX 2052 were to be presented to the jury — which they should not — TRX 2053 is redundant and cumulative of those exhibits and therefore should not be presented.
2054	~~Proposed protocol for the r-HuEPO Phase I study~~	1. This reference came into existence after the date of Dr. Lin's inventions and therefore does not meet the Court's criterion as *prior* art (See 10/4/07 Trial Tr. 152:3-7.) 2. Roche failed to disclose TRX 2054 pursuant to 35 U.S.C. § 282. 3. To the extent that 2054 is based on Dr. Lin's claimed inventions, it cannot constitute prior art. 4. Given Roche's failure to specify precisely what in this reference purportedly anticipates precisely which claims in suit, Amgen objects to Roche's characterization of this exhibit as anticipatory prior art.
2060	~~Egrie et at, "Characterization of Recombinant Human and Monkey Erythropoietin" Abstract from 10th Annual Fredrick Stohlman Memorial Symposium on Stem Cell Physiology, Boston, MA (1984)~~	1. This reference came into existence after the date of Dr. Lin's inventions and therefore does not meet the Court's criterion as *prior* art (See 10/4/07 Trial Tr. 152:3-7.) 2. To the extent that 2060 is based on Dr. Lin's claimed inventions, it cannot constitute prior art. 3. Given Roche's failure to specify precisely what in this reference purportedly anticipates precisely which claims in suit, Amgen objects to Roche's characterization of this exhibit as anticipatory prior art. 4. Assuming either TRX 2068 or TRX 2079 were to be presented to the jury — which they should not — TRX 2060 is redundant and cumulative of those exhibits and therefore should not be presented.
2068	~~Egrie et at, "Characterization of Recombinant Human and Monkey Erythropoietin" Abstract from 10th Annual Fredrick Stohlman Memorial Symposium on Stem Cell Physiology, Boston, MA~~	1. See reasons for removal re TRX 2060, above.

TRX	DESCRIPTION	Reasons for Removal from List
	~~(1984)~~	
2079	~~Egrie et al, "Characterization of Recombinant Human and Monkey Erythropoietin" Abstract from 10th Annual Fredrick Stohlman Memorial Symposium on Stem Cell Physiology, Boston, MA (1984)~~	1. See reasons for removal re TRX 2060, above.
2084	~~Notebook 193 (Edward Fritsch)~~	1. This reference came into existence after the date of Dr. Lin's inventions and therefore does not meet the Court's criterion as *prior* art (See 10/4/07 Trial Tr. 152:3-7.) 2. Roche failed to disclose TRX 2084 pursuant to 35 U.S.C. § 282. 3. Given Roche's failure to specify precisely what in this reference purportedly anticipates precisely which claims in suit, Amgen objects to Roche's characterization of this exhibit as anticipatory prior art. 4. To the extent that Roche asserts that the claimed inventions are somehow anticipated by any purported description of cloning and expression of the human EPO gene in TRX 2084, since it is indisputable that Dr. Lin cloned the human EPO gene in October 1983, and achieved the expression of *in vivo* biologically active human EPO by March 1984, TRX 2084 is not prior art.
2088	~~Goldwasser Grant Application re Erythropoietin: Purification Properties Biogenesis~~	1. See reasons for removal re TRX 0008, above. 2. This reference came into existence after the date of Dr. Lin's inventions and therefore does not meet the Court's criterion as *prior* art (See 10/4/07 Trial Tr. 152:3-7.) 3. Given Roche's failure to specify precisely what in this reference purportedly anticipates precisely which claims in suit, Amgen objects to Roche's characterization of this exhibit as anticipatory prior art. 4. To the extent that Roche asserts that the claimed inventions are somehow anticipated by any purported description of cloning and expression of the human EPO gene in TRX 2088, since it is indisputable that Dr. Lin cloned the human EPO gene in October 1983, and achieved the expression of *in vivo* biologically active human EPO by March 1984, TRX 2084 is not prior art.
2090	~~Collaboration Agreement between T. Miyake and Genetics Institute (signed)~~	1. This reference came into existence after the date of Dr. Lin's inventions and therefore does not meet the Court's criterion as *prior* art (See 10/4/07 Trial Tr. 152:3-7.) 2. Roche failed to disclose TRX 2090 pursuant to 35 U.S.C. § 282. 3. Given Roche's failure to specify precisely what in this reference purportedly anticipates precisely which claims in suit, Amgen objects to Roche's

TRX	DESCRIPTION	Reasons for Removal from List
		characterization of this exhibit as anticipatory prior art. 4. To the extent that Roche asserts that the claimed inventions are somehow anticipated by any purported description of the cloning and expression of the human EPO gene in TRX 2090, since it is indisputable that Dr. Lin cloned the human EPO gene in October 1983, and achieved the expression of *in vivo* biologically active human EPO by March 1984, TRX 2090 is not prior art.

III. LIST REGARDING THE EXHIBITS WHICH ALLEGEDLY CONSTITUTE PRIOR ART

As the annotated list set forth below regarding the exhibits which allegedly constitute prior art reflects, the parties were able to come to agreement on a number of exhibits (*see, e.g.*, TRX 2024, 2026, 2028, 2029, 2030, 2034, 10, 11, 12, 13, 14, 39, 41, 43, 49, 2001, 2002, 2010, 2013.317, 2018, 2019, 2020, 2021, 2022, 2023, 2025, 2031, 2033, 2048, 2073, 2075, 2076, 2077, 2078, 2080, 2081, 2082, 2095, 2099, 2101, 2102, 2103, and 2104). As to the remaining exhibits, however, the parties were unable to come to agreement as these exhibits suffer from many of the same defects discussed above.

TRX	DESCRIPTION	REASONS FOR REMOVAL FROM LIST
2068	~~Egrie et al, "Characterization of Recombinant Human and Monkey Erythropoietin" Abstract from 10th Annual Fredrick Stohlman Memorial Symposium on Stem Cell Physiology, Boston, MA (1984)~~	Not prior art. Amgen's own work. Cumulative and redundant.
2071	~~Egrie Laboratory Notebook No. 448~~	Not prior art. Not public. Not relevant. Amgen's own work.
2072	~~Letter from Egrie to Gaylis re Finally Finished the EPO RIAs on Last Set of Samples Sent~~	Not prior art Not public. Not relelvant. Amgen's own work.
2073	E. Goldwasser & J. Sherwood, "Annotation Radioimmunoassay of Erythropoietin," Brit. J. Haematol., 48:359-363 (1981)	
2075	Ascensao et al, "Erythropoietin Production by a Human Testicular Germ Cell Line," Blood 62(5):1132-34 (1983)	
2076	Beaucage et al. (1981) "Deoxynucleoside Phosphoramidites--A new Class of Key Intermediates for Deoxypolynucleotide Synthesis," Tetrahedron Letters, 22(20), 1859-1862 (1981)	

TRX	DESCRIPTION	REASONS FOR REMOVAL FROM LIST
2077	Edge et al, "Total synthesis of a human leukocyte interferon gene," Nature 292(5825):756-62 (1981)	
2078	Edge, M.D., et al . (1983) "Chemical synthesis of a human interferon-alpha 2 gene and its expression in Escherichia coli," Nucleic Acids Res. 11(18):6419-35 (1983)	
2079	~~Egrie et al, "Characterization of Recombinant Human and Monkey Erythropoietin" Abstract from 10th Annual Fredrick Stohlman Memorial Symposium on Stem Cell Physiology, Boston, MA (1984)~~	Not prior art. Amgen's own work. Cumulative and redundant.
2080	Farber and Zanjani, "Translation of mRNA from Anemic Baboon Kidney into Biologically Active Erythropoietin," Exp Hematol. 11 (S14):57 (1983)	
2081	Glanville et al, "Completion of the amino acid sequence of the al chain from type I calf skin collagen," The Biochem. J. 215:183-189 (1983)	
2082	Sherwood and Goldwasser, "A radioimmunoassay for erythropoietin," Blood 54 (4):885-893 (1979)	
2084	~~Notebook 193 (Edward Fritsch)~~	Not prior art. Not disclosed pursuant to 35 U.S.C. §282
2085	~~Memorandum to J. Fenno, N. Stebbing from D. Vapnek RE: IND~~	Not prior art. Not public. Not relevant.
2088	~~Goldwasser Grant Application re Erythropoietin: Purification Properties Biogenesis~~	Not prior art. Not public.
2090	~~Collaboration Agreement between T. Miyake and Genetics Institute (signed)~~	Not prior art. Not public.
2091	~~Memorandum to J. Fenno and N. Stebbing from D. Vapnek RE: IND for EPO~~	Not prior art. Not public. Not relevant.
2093	~~Molecular Cloning and Characterization of the Gene Encoding Erythropoietin, Daniel Vapnek~~	Not prior art. Amgen's own work.
2095	Farber and Zanjani, "Translation of mRNA from Human Kidneys into Biologically Active Erythropoietin Following Microinjection into Xenopus Laevis Oocytes," Blood 62(5) (Supp. 1):122a, Abstract No. 392 (1983)	
2097	~~Notice of Grant Award - The Developmental Biology of Human Erythropoiesis from 07.01.81-06 .30 .86 (renewal)~~	Not public.
2098	~~Orkin S.H., et. al., Molecular cloning of human adenosine deaminase gene sequences. J. Biol. Chem., 258:12753-12756~~	Not prior art
2099	Michelson, A.M., et al., Isolation of DNA sequence of a full-legnth cDNA clone for human X chromosome-encoded phosphoglycerate kinase. J. Biol. Chem., 80:472-476, 1983	
2100	~~Notice of Grant Award - The Developmental Biology of Human Erythropoiesis from 07.01.81-06 .30 .86~~	Not public.

TRX	DESCRIPTION	REASONS FOR REMOVAL FROM LIST
2101	Lawn et al. (1978) "The Isolation and Characterization of Linked .delta.- and.beta.-Globin Genes from a Cloned Library of Human DNA," Cell, 15, 1157-1174 (Dec. 1978)	
2102	American Type Culture Collection ("ATCC"), Catalogue of Cell Lines, Viruses, and Antisera, 4th ed . (1983)	
2103	Wallace et al, "The use of synthetic oligonucleotides as hybridization probes. II Hybridization of oligonucleotides of mixed sequence to rabbit a-gobin DNA," Nucleic Acids Res. 9(4):879-894 (1981)	
2104	Urlaub and Chasin, "Isolation of Chinese hamster cell mutants deficient in dihydrofolate reductase activity," PNAS 77:4216-4220 (1980)	
2068	~~Egrie et al, "Characterization of Recombinant Human and Monkey Erythropoietin" Abstract from 10th Annual Fredrick Stohlman Memorial Symposium on Stem Cell Physiology, Boston, MA (1984)~~	Not prior art. Amgen's own work. Cumulative and redundant.
2071	~~Egrie Laboratory Notebook No. 448~~	Not prior art. Not public. Not relevant. Amgen's own work.
2072	~~Letter from Egrie to Gaylis re Finally Finished the EPO RIAs on Last Set of Samples Sent~~	Not prior art Not public. Not relelvant. Amgen's own work.
2073	E. Goldwasser & J. Sherwood, "Annotation Radioimmunoassay of Erythropoietin," Brit. J. Haematol., 48:359-363 (1981)	
2075	Ascensao et al, "Erythropoietin Production by a Human Testicular Germ Cell Line," Blood 62(5):1132-34 (1983)	
2076	Beaucage et al. (1981) "Deoxynucleoside Phosphoramidites--A new Class of Key Intermediates for Deoxypolynucleotide Synthesis," Tetrahedron Letters, 22(20), 1859-1862 (1981)	
2077	Edge et al, "Total synthesis of a human leukocyte interferon gene," Nature 292(5825):756-62 (1981)	
2078	Edge, M.D., et al . (1983) "Chemical synthesis of a human interferon-alpha 2 gene and its expression in Escherichia coli," Nucleic Acids Res. 11(18):6419-35 (1983)	
2079	~~Egrie et al, "Characterization of Recombinant Human and Monkey Erythropoietin" Abstract from 10th Annual Fredrick Stohlman Memorial Symposium on Stem Cell Physiology, Boston, MA (1984)~~	Not prior art. Amgen's own work. Cumulative and redundant.
2080	Farber and Zanjani, "Translation of mRNA from Anemic Baboon Kidney into Biologically Active Erythropoietin," Exp Hematol. 11 (S14):57 (1983)	
2081	Glanville et al, "Completion of the amino acid sequence of the al chain from type I calf skin collagen," The Biochem. J. 215:183-189 (1983)	
2082	Sherwood and Goldwasser, "A radioimmunoassay for erythropoietin," Blood 54 (4):885-893 (1979)	
2084	~~Notebook 193 (Edward Fritsch)~~	Not prior art. Not disclosed

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		pursuant to 35 U.S.C. §282
2085	~~Memorandum to J. Fenno, N. Stebbing from D. Vapnek RE: IND~~	Not prior art. Not public. Not relevant.
2088	~~Goldwasser Grant Application re Erythropoietin: Purification Properties Biogenesis~~	Not prior art. Not public.
2090	~~Collaboration Agreement between T. Miyake and Genetics Institute (signed)~~	Not prior art. Not public.
2091	~~Memorandum to J. Fenno and N. Stebbing from D. Vapnek RE: IND for EPO~~	Not prior art. Not public. Not relevant.
2093	~~Molecular Cloning and Characterization of the Gene Encoding Erythropoietin, Daniel Vapnek~~	Not prior art. Amgen's own work.
2095	Farber and Zanjani, "Translation of mRNA from Human Kidneys into Biologically Active Erythropoietin Following Microinjection into Xenopus Laevis Oocytes," Blood 62(5) (Supp. 1):122a, Abstract No. 392 (1983)	
2097	~~Notice of Grant Award - The Developmental Biology of Human Erythropoiesis from 07.01.81-06 .30 .86 (renewal)~~	Not public.
2098	~~Orkin S.H., et. al., Molecular cloning of human adenosine deaminase gene sequences. J. Biol. Chem., 258:12753-12756~~	Not prior art
2099	Michelson, A.M., et al., Isolation of DNA sequence of a full-legnth cDNA clone for human X chromosome-encoded phosphoglycerate kinase. J. Biol. Chem., 80:472-476, 1983	
2100	~~Notice of Grant Award - The Developmental Biology of Human Erythropoiesis from 07.01.81-06 .30 .86~~	Not public.
2101	Lawn et al. (1978) "The Isolation and Characterization of Linked .delta.- and.beta.-Globin Genes from a Cloned Library of Human DNA," Cell, 15, 1157-1174 (Dec. 1978)	
2102	American Type Culture Collection ("ATCC"), Catalogue of Cell Lines, Viruses, and Antisera, 4th ed . (1983)	
2103	Wallace et al, "The use of synthetic oligonucleotides as hybridization probes. II Hybridization of oligonucleotides of mixed sequence to rabbit a-gobin DNA," Nucleic Acids Res. 9(4):879-894 (1981)	
2104	Urlaub and Chasin, "Isolation of Chinese hamster cell mutants deficient in dihydrofolate reductase activity," PNAS 77:4216-4220 (1980)	

October 10, 2007

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

/s/ Michael R. Gottfried

D. DENNIS ALLEGRETTI (BBO#545511)
MICHAEL R. GOTTFRIED (BBO#542156)
PATRICIA R. RICH (BBO#640578)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (857) 488-4200
Facsimile: (857) 488-4201

Of Counsel:

STUART L. WATT
WENDY A. WHITEFORD
MONIQUE L. CORDRAY
DARRELL G. DOTSON
KIMBERLIN L. MORLEY
ERICA S. OLSON

AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-5000

LLOYD R. DAY, JR. (*pro hac vice*)
DAY CASEBEER
MADRID & BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

WILLIAM GAEDE III (*pro hac vice*)
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

KEVIN M. FLOWERS (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as on-registered participants.

/s/ Michael R. Gottfried
Michael R. Gottfried