#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

LUKASHEV et al.

Appl. No.: To be assigned

(Continuation of Appl. No. 12/526,296; § 371(c) Date: January 13, 2011)

Filed: Herewith

For: Treatment for Multiple Sclerosis

(As Amended)

Confirmation No.: To be assigned

Art Unit: To be assigned

Examiner: To be assigned

Atty. Docket: 2159.3210002/JMC/MRG/U-S

#### First Supplemental Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms PTO/SB/08a equivalent and/or PTO/SB/08b equivalent are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. §1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

Applicants have checked the appropriate boxes below.

- ☐ 1. Statement under 37 C.F.R. 1.704(d). Each item of information contained in this
  Information Disclosure Statement was first cited in a communication from a
  foreign patent office in a counterpart application and this communication was not
  received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty
  days prior to the filing of this information disclosure statement.

Atty. Dkt. No. 2159.3210002/JMC/MRG/U-S

3. Filing under 37 C.F.R. § 1.97(c). This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1). b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2). c. Attached is our PTO-2038 Credit Card Payment Form in the amount of \$180.00 in payment of the fee under 37 C.F.R. §

1.17(p).

Atty. Dkt. No. 2159.3210002/JMC/MRG/U-S

- ☐ 4. Filing under 37 C.F.R. § 1.97(d) This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but on or before payment of the Issue Fee. Enclosed find our PTO-2038 Credit Card Payment Form in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p); in addition:
  - □ a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
  - b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- 5. The document(s) was/were cited in a search report by a foreign patent office in a counterpart foreign application. Submission of an English language version of the search report that indicates the degree of relevance found by the foreign office

is provided in satisfaction of the requirement for a concise explanation of relevance. 1138 OG 37, 38 and MPEP 609.04(a)(III).

A concise explanation of the relevance of the non-English language documents
 appears below in accordance with 37 C.F.R. 

§ 1.98(a)(3).

Document FP1, JP 54-80439 A, is in the Japanese language. An English language abstract of document FP1 is cited as document NPL1 and submitted herewith.

Document FP2, EP 0 188 749 A2, is in the German language. Document US3 is believed to be an English-language equivalent of document FP2.

Document FP4, EP 0 312 697 A2, is in the German language. Document US4 is believed to be an English-language equivalent of document FP4.

Document FP5, DE 38 34 794 A1, is in the German language. An English language abstract of document FP5 is cited as document NPL2 and submitted herewith.

Document FP6, EP 0 518 388 A2, is in the German language. Document US4 is believed to be an English-language equivalent of document FP6.

Document FP7, JP 6-345644 A, is in the Japanese language. An English language abstract of document FP7 is cited as document NPL3 and submitted herewith.

Document FP9, JP 8-99906 A, is in the Japanese language. An English language abstract of document FP9 is cited as document NPL4 and submitted herewith.

Document FP13, JP 9-221428 A, is in the Japanese language. An English language abstract of document FP13 is cited as document NPL5 and submitted herewith.

Document FP15, WO 97/48405 A1, is in the Russian language. An English language abstract of document FP15 is cited as document NPL6 and submitted herewith.

Document FP19, DE 197 21 099 A1, is in the German language. Document US14 is believed to be an English-language equivalent of document FP19.

Document FP23, RU 2 189 813 C1, is in the Russian language. An English language abstract of document FP23 is cited as document NPL7 and submitted herewith.

Document FP25, WO 2005/027899 A1, is in the German language. An English language abstract of document FP25 is cited as document NPL8 and submitted herewith.

Document FP37, CN 1125141 A, is in the Chinese language. An English language abstract of document FP37 is cited as document NPL292 and submitted herewith.

Document NPL28, Dücker and Pfeiff, is in the German language. An English language abstract of document NPL28 can be found on the face page of the publication.

Document **NPL31**, **Fliegner and Spiegel**, is in the German language. An English language abstract of document NPL31 can be found on the face page of the publication.

Document NPL48, Hunziker and Schmidli, is in the German language. It is believed that document NPL47 is a partial English language translation of document NPL48.

Document NPL163, Gutzmer et al., is in the German language. An English language abstract of Document NPL163 is cited as document NPL164 and submitted herewith.

Document **NPL165**, **Hagedorn** *et al.*, is in the German language. An English language abstract of document NPL165 can be found on the face page of the publication.

Document **NPL187**, **Roodnat** *et al.*, is in the German language. An English language abstract of document NPL187 can be found on the face page of the publication.

Document **NPL191**, **Schilling and Schopf**, is in the German language. An English language abstract of document NPL191 can be found on the face page of the publication.

Document NPL198, Van Loenen et al., is in the Dutch language. An English language abstract of document NPL198 can be found on the face page of the publication.

Document **NPL202**, **Wanscher and Sørensen**, is in the Danish language. An English language abstract of document NPL202 can be found on the page 6357 of the publication.

Document **NPL210**, *Immunmodulation durch Fumaderm*. *Das richtungsweisende Konzept*, is in the German language. It is believed that document **NPL211** is a partial English language translation of document NPL210.

Document NPL215, Bayard et al., is in the German language. An English language abstract of document NPL215 can be found on the face page of the publication.

Document NPL234, "Klinische Studie mit Fumaderm® als magensaftresistente Mikrotabletten," the first three pages are in the German language. An English language translation of pages 1-3 of document NPL234 can be found on pages 4-6 of the same document.

Document NPL247, Peeters et al., is in the Dutch language. An English language abstract of document NPL247 can be found on the last page of the publication.

Document NPL257, Stangel et al., is in the German language. An English language abstract of document NPL257 can be found on page 215 of the publication.

Document NPL258, Stühlinger et al., is in the German language. An English language abstract of document NPL258 can be found on the face page of the publication.

- 7. Copies of the documents are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), no copies of U.S. patents and patent application publications cited as documents US1-US40 on the attached IDS Forms are submitted.
- No. 12/526,296, with a § 371(c) date of January 13, 2011, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).
- ∑ 9. It is expected that the examiner will review the prosecution and cited art in the parent application no. 12/526,296 in accordance with MPEP 2001.06(b), and indicate in the next communication from the office that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

Atty. Dkt. No. 2159.3210002/JMC/MRG/U-S

371(c) date July 8, 1999; 09/402,103, § 371(c) date September 27, 1999; 09/743,978, § 371(c) date January 17, 2001; 09/831,620, § 371(c) date May 10, 2001; 10/148,858, § 371(c) date May 28, 2002; 10/197,077, filed July 17, 2002; 11/765,563, filed June 20, 2007; 11/765,578, filed June 20, 2007; 12/405,661, filed March 17, 2009; and 12/405,665, filed March 17, 2009, as documents **NPL269-NPL291**.

The identification of these Office Actions is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Marsha A. Rose

Attorney for Applicants Registration No. 58,403

Date: 2 3 2012

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

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#### FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known					
Application Number	To be assigned				
Filing Date	Herewith				
First Named Inventor	Matvey E. LUKASHEV				
Art Unit	To be assigned				
Examiner Name	To be assigned				
Attorney Docket Number	2159.3210002/JMC/MRG/U-S				

Examiner	Cite	Document Number		T DOCUMENTS	
- Administra	No.1	Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US1	4,515,974	05-07-1985	Zecher et al.	
	US2	4,746,668	05-24-1988	Sato et al.	
	US3	4,851,439	07-25-1989	Speiser et al.	
	US4	4,959,389	09-25-1990	Speiser et al.	
	US5	5,149,695	09-22-1992	Speiser et al.	
	US6	5,214,196	05-25-1993	Blank	
	US7	5,242,905	09-07-1993	Blank	
	US8	5,359,128	10-25-1994	Blank	
	US9	5,424,332	06-13-1995	Speiser et al.	
	US10	5,451,667	09-19-1995	Speiser et al.	
	US11	6,277,882 B1	08-21-2001	Joshi et al.	
	US12	6,355,676 B1	03-12-2002	Joshi <i>et al</i> .	
	US13	6,359,003 B1	03-19-2002	Joshi et al.	
	US14	6,436,992 B1	08-20-2002	Joshi <i>et al</i> .	
	US15	6,509,376 B1	01-21-2003	Joshi <i>et al</i> .	
	US16	6,858,750 B2	02-22-2005	Joshi <i>et al.</i>	
	US17	7,157,423 B2	01-02-2007	Joshi <i>et al</i> .	
	US18	7,320,999 B2	01-22-2008	Joshi et al.	
	US19	7,432,240 B2	10-07-2008	Joshi et al.	
	US20	7,612,110 B2	11-03-2009	Joshi et al.	

			FOREIGN P	ATENT DOCUMENTS		
Examiner initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind  Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	ŢĆ
	FP1	JP 54-80439 A	06-27-1979	Ogawa Hiroe		
	FP2	EP 0 188 749 A2	07-30-1986	Speiser et al.		
	FP3	WO 89/01930 A1	03-09-1989	Dexter Biotechnics		
	FP4	EP 0 312 697 A2	04-26-1989	Speiser et al.		
	FP5	DE 38 34 794 A1	04-19-1990	Schielein, F.		
	FP6	EP 0 518 388 A2	12-16-1992	Speiser et al.		
	FP7	JP 6-345644 A	12-20-1994	Unitika Ltd.		
	FP8	WO 94/28883 A1	12-22-1994	Brown, Raymond		

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Examiner	Date	
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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO Complete if Known Application Number To be assigned FIRST SUPPLEMENTAL Filing Date Herewith INFORMATION DISCLOSURE First Named Inventor Matvey E. LUKASHEV STATEMENT BY APPLICANT Art Unit To be assigned (Use as many sheets as necessary) Examiner Name To be assigned Sheet of Attorney Docket Number 2159.3210002/JMC/MRG/U-S

			U.S. PATEN	T DOCUMENTS	×
Examiner initials*	Cite No. <sup>1</sup>	Document Number  Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US21	7,619,001 B2	11-17-2009	Joshi et al.	
	US22	7,790,916 B2	09-07-2010	Joshi et al.	
	US23	7,803,840 B2	09-28-2010	Joshi <i>et al</i> .	
	US24	7,915,310 B2	03-29-2011	Joshi <i>et al.</i>	
	US25	2004/0054001 A1	03-18-2004	Joshi <i>et al</i> .	
	US26	2008/0233185 A1	09-25-2008	Joshi <i>et al.</i>	
	US27	2010/0130607 A1	05-27-2010	Gold	
	US28	5,538,968	07-23-1996	Chiesi et al.	
	US29	5,548,059	08-20-1996	Bayley et al.	
	US30	5,972,363	10-26-1999	Clikeman et al.	
	US31	6,812,248 B2	11-02-2004	Zhang et al.	
	US32	7,056,950 B2	06-06-2006	Rath	
	US33	7,279,331 B2	10-09-2007	Black et al.	
	US34	7,364,900 B2	04-29-2008	Black et al.	
	US35	7,417,045 B2	08-26-2008	Anilkumar et al.	
	US36	7,638,119 B2	12-29-2009	Johnson <i>et al</i> .	
***************************************	US37	7,871,977 B2	01-18-2011	Rischer et al.	
~~~~	US38	2003/0176365 A1	09-18-2003	Blass	
	US39	2005/0245612 A1	11-03-2005	Blass	
	US40	2008/0089861 A1	04-17-2008	Went et al.	

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Examiner initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -  Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentes or Applicant of Cited Document	Pages, Columus, Lines, Where Relevant Passages or Relevant Figures Appear	T6
	FP9	JP 8-99906 A	04-16-1996	Chugai Pharmaceutical Co., Ltd.		
	FP10	WO 97/09984 A1	03-20-1997	Takeda Chemical Industries, Ltd.		
	FP11	WO 97/13504 A1	04-17-1997	Medgene Limited		
	FP12	CA 2,248,955 A1	05-20-1997	Fumapharm AG		
	FP13	JP 9-221428 A	08-26-1997	Fujisawa Pharmaceutical Co.		
	FP14	WO 97/44054 A2	11-27-1997	University of Alberta		
	FP15	WO 97/48405 A1	12-24-1997	Belyaev, Jury Evgenievich		
	FP16	WO 98/04290 A2	02-05-1998	Perrine et al.		

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Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO	Complete if Known		
FIRST SUPPLEMENTAL	Application Number	To be assigned	
INFORMATION DISCLOSURE	Filing Date	Herewith	
	First Named Inventor	Matvey E. LUKASHEV	
STATEMENT BY APPLICANT	Art Unit	To be assigned	
(Use as many sheets as necessary)	Examiner Name	To be assigned	
Sheet 3 of 7	Attorney Docket Number	2159.3210002/JMC/MRG/U-S	

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Examiner initials*	No.1	Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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initials* No.1	Country Code <sup>3</sup> -Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)	Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T	
	FP17	WO 98/27970 A2	07-02-1998	National Research Council of Canada		
:	FP18	EP 0 852 233 A1	07-08-1998	Nippon Shinyaku Company, Limited		
	FP19	DE 197 21 099 A1	11-26-1998	Fumapharm AG		
	FP20	WO 99/21565 A1	05-06-1999	Cornell Research Foundation, Inc.		
	FP21	WO 01/59072 A1	08-16-2001	Philadelphia Health and Education Corporation; University of Medicine and Dentistry of New Jersey		
	FP22	WO 02/02190 A2	01-10-2002	Johns Hopkins School of Medicine		
	FP23	RU 2 189 813 C1	09-27-2002	Rossijskij NII Gematologii Transfuziologii		
	FP24	WO 03/032969 A2	04-24-2003	National Research Council of Canada		Γ

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

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STATEMENT BY APPLICANT		Art Unit	To be assigned			
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Sheet	4	of	7		Attorney Docket Number	2159.3210002/JMC/MRG/U-S

	U.S. PATENT DOCUMENTS							
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	FP25	WO 2005/027899 A1	03-31-2005	Heidland, August			
	FP26	WO 2006/037342 A2	04-13-2006	Aditech Pharma AB			
	FP27	WO 2006/050730 A1	05-18-2006	Aditech Pharma AB			
-	FP28	WO 2006/055871 A2	05-26-2006	Biogen Idec MA Inc.			
	FP29	WO 2007/006307 A2	01-18-2007	Aditech Pharma AB			
***************************************	FP30	WO 2007/042035 A2	04-19-2007	Aditech Pharma AB			
	FP31	WO 2008/096271 A2	08-14-2008	Gold, Ralf			
-	FP32	WO 2008/097596 A2	08-14-2008	Biogen Idec MA Inc.			

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE	First Named Inventor	Matvey E. LUKASHEV
STATEMENT BY APPLICANT	Art Unit	To be assigned
(Use as many sheets as necessary)	Examiner Name	To be assigned
Sheet 5 of 7	Attorney Docket Number	2159.3210002/JMC/MRG/U-S

			U.S. PATEN	T DOCUMENTS	
Examiner	Cite No. 1	Document Number	- Publication Date	Name of Patentee or	Pages, Columns, Lines, Where
initials*	Cite No.	Number-Kind Code <sup>2 (if</sup> known)	MM-DD-YYYY	Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages of Relevant Figures Appear
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Examiner initials* Cite No	Cite No.1	Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Date MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	Т6
	FP33	WO 95/25102 A1	09-21-1995	Novo Nordisk A/S		
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	FP34	WO 96/01122 A1	01-18-1996	Dana-Farber Cancer Institute		
	FP35	GB 2 291 422 A	01-24-1996	Fujisawa Pharmaceutical Co., Ltd		
	FP36	WO 96/08970 A1	03-28-1996	The Trustees of the University of Pennsylvania; Apollon, Inc.		
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Attorney Docket Number

Complete if Known				
Application Number	To be assigned			
Filing Date	Herewith			
First Named Inventor	Matvey E. LUKASHEV			
Art Unit	To be assigned			
Examiner Name	To be assigned			
Attorney Docket Number	2159.3210002/JMC/MRG/U-S			

			U.S. PATEN	T DOCUMENTS	**************************************
Examiner		Document Number	Publication Date	N CD.	2 01
initials*	Cite No. 1	Number-Kind Code <sup>2</sup> (if known)	MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

			FOREIGN	PATENT DOCUMENTS		
Examiner	Cite	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines, Where	
initials*		Country Code <sup>3</sup> -Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)	Date MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	Т6
	FP41	WO 03/020908 A2	03-13-2003	University of Medicine and Dentistry of New Jersey		
	FP42	WO 2005/023241 A1	03-17-2005	Fumapharm AG		
	FP43	WO 2006/088836 A2	08-24-2006	Schering Corporation; Pharmacopeia Drug Discovery, Inc.		
	FP44	WO 2006/088837 A2	08-24-2006	Schering Corporation; Pharmacopeia Drug Discovery, Inc.		
	FP45	WO 2006/088840 A1	08-24-2006	Schering Corporation; Pharmacopeia Drug Discovery, Inc.		
	FP46	WO 2006/088919 A2	08-24-2006	Schering Corporation; Pharmacopeia Drug Discovery, Inc.		
	FP47	WO 2006/088920 A1	08-24-2006	Schering Corporation; Pharmacopeia Drug Discovery, Inc.		
	FP48	WO 2006/088921 A2	08-24-2006	Schering Corporation; Pharmacopeia Drug Discovery, Inc.		

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Application Number	To be assigned		
Filing Date	Herewith		
First Named Inventor	Matvey E. LUKASHEV		
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			FOREIGN I	PATENT DOCUMENTS		
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	No.1	Country Code <sup>3</sup> -Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)	Date MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	
	FP49	WO 2006/091428 A2	08-31-2006	Schering Corporation; Pharmacopeia Drug Discovery, Inc.		
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		NON PATENT LITERATURE DOCUMENTS	
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	NPL1	Thomson Innovation Patent Record, DWPI Accession No. 1979-58797B, English language Abstract of Japanese Patent Publication No. 54-80439 A, (1979)	Abs.
:	NPL2	English language Abstract of German Patent Publication No. DE 38 34 794 A1, European Patent Office, Espacenet database — Worldwide (2001)	Abs.
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FIRST SUPPLEMENTAL					Application Number	To be assigned		
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					First Named Inventor	Matvey E. LUKASHEV		
i .	STATEMENT BY APPLICANT				Art Unit	To be assigned		
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Sheet	4	of	30		Attorney Docket Number	2159.3210002/JMC/MRG/U-S		

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	NPL32	FURLAN, R., et al., "Interferon-β treatment in multiple sclerosis patients decreases the number of circulating T cells producing interferon-γ and interleukin-4," J. Neuroimmunol. 111:86-92, Elsevier Science B.V., Netherlands (2000)	
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:	NPL37	GHORESCHI, K., et al., "Fumarates induce a DC2 phenotype in dendritic cells that establishes protective Th2 responses," Arch. Dermatol. Forschung 296:420, Springer Verlag, Germany (2005) (Abstract Only)	Abs.
	NPL38	GHORESCHI, K., et al., "Fumaric acid ester an antipsoriatic drug abolishes the capacity of T cells to induce Th1-mediated autoimmune disease," Arch. Dermatol. Res. 294:28, Springer Verlag, Germany (2002) (Abstract Only)	Abs.
	NPL39	GIELEN, A.W., et al., "Expression of T cell immunoglobulin- and mucin-domain-containing molecules-1 and -3 (TIM-1 and -3) in the rat nervous and immune systems," J. Neuroimmunol. 164:93-104, Elsevier B.V., Netherlands (2005)	
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First Named Inventor	Matvey E. LUKASHEV		
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	NPL41	GIOVANNONI, G. and MILLER, D.H., "Multiple sclerosis and its treatment," J. R. Coll. Physicians Lond. 33(4):315-322, Royal College of Physicians, England (1999)	
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Application Number

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FIRST SUPPLEMENTAL	Application Number	To be assigned
INFORMATION DISCLOSURE	Filing Date	Herewith
•	First Named Inventor	Matvey E. LUKASHEV
STATEMENT BY APPLICANT	Art Unit	To be assigned
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		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	$T^2$
	NPL61	KRAKOWSKI, M. and OWENS, T., "Interferon-γ confers resistance to experimental allergic encephalomyelitis," <i>Eur. J. Immunol.</i> 26:1641-1646, VCH Verlagsgesellschaft mbH, Germany (1996)	,
	NPL62	KURODA, K., et al., "Fumaric Acid Enhances DNA Synthesis of Rat Hepatocytes by Counteracting the Toxicities of Mitomycin C and Aflatoxin B <sub>1</sub> ," <i>Jpn. J. Cancer Res.</i> (Gann) 77:750-758, Japanese Cancer Association, Japan (1986)	
	NPL63	LAFAILLE, J.J., et al., "Myelin Basic Protein-specific T Helper 2 (Th2) Cells Cause Experimental Autoimmune Encephalomyelitis in Immunodeficient Hosts Rather than Protect Them from the Disease," J. Exp. Med. 186(2):307-312, The Rockefeller University Press, United States (1997)	
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**************************************	NPL65	LAHTI, A. and MAIBACH, H.I., "Contact urticaria from diethyl fumarate," <i>Contact Dermatitis 12</i> :139-140, Munksgaard, Denmark (1985)	-
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	NPL68	LIEDTKE, W., et al., "Effective Treatment of Models of Multiple Sclerosis by Matrix Metalloproteinase Inhibitors," Ann. Neurol. 44(1):35-46, The American Neurological Association, United States (1998)	-
:	NPL69	LINK, J., et al., "Organ-specific autoantigens induce interferon-γ and interleukin-4 mRNA expression in mononuclear cells in multiple sclerosis and myasthenia gravis," Neurology 44:728-734, The American Academy of Neurology, United States (1994)	
	NPL70	LINK, J., et al., "Organ-specific Autoantigens Induce Transforming Growth Factor-β mRNA Expression in Mononuclear Cells in Multiple Sclerosis and Myasthenia Gravis," <i>Annals Neurol.</i> 35:197-203, The American Neurological Association, United States (1994)	

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	NPL71	LINK, J., <i>et al.</i> , "Optic neuritis is associated with myelin basic protein and proteolipid protein reactive cells producing interferon-γ, interleukin-4 and transforming growth factor-β," <i>J. Neuroimmunol.</i> 49:9-18, Elsevier Science B.V., Netherlands (1994)	
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	NPL76	LOBELL, A., et al., "Vaccination with DNA Encoding an Immunodominant Myelin Basic Protein Peptide Targeted to Fc of Immunoglobulin G Suppresses Experimental Autoimmune Encephalomyelitis," <i>J. Exp. Med.</i> 187(9):1543-1548, The Rockefeller University Press, United States (1998)	
:	NPL77	LOPEZ, E., et al., "Interferon γ, IL2, IL4, IL10 and TNFα Secretions in Multiple Sclerosis Patients Treated with an Anti-CD4 Monoclonal Antibody," Autoimmunity 29:87-92, OPA (Overseas Publishers Association) N.V., England (1999)	
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	NPL80	LYONS, JA., et al., "Pathogenesis of acute passive murine encephalomyelitis II. Th1 phenotype of the inducing population is not sufficient to cause disease," <i>J. Neuroimmunol.</i> 93:26-36, Elsevier Science B.V., Netherlands (1999)	

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		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	appropriate) title of the item (heals managing insured assist		
	NPL81	MÄÄTTÄ, J.A., et al., "Neutrophils secreting tumor necrosis factor alpha infiltrate the central nervous system of BALB/c mice with experimental autoimmune encephalomyelitis," <i>J. Neuroimmunol.</i> 90:162-175, Elsevier Science B.V., Netherlands (1998)	***************************************
	NPL82	MARTIN, R., et al., "T helper cell differentiation in multiple sclerosis and autoimmunity," <i>Immunol. Today 19(11)</i> :495-498, Elsevier Science, England (1998)	***************************************
	NPL83	MATTNER, F., et al., "Inhibition of Th1 development and treatment of chronic-relapsing experimental allergic encephalomyelitis by a non-hypercalcemic analogue of 1,25-dihydroxyvitamin D <sub>3</sub> ," Eur. J. Immunol. 30:498-508, WILEY-VCH Verlag GmbH, Germany (2000)	
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	NPL85	ASADULLAH, K., et al., "Influence of monomethylfumarate on monocytic cytokine formation - explanation for adverse and therapeutic effects in psoriasis?" Arch. Dermatol. Res. 289:623-630, Springer-Verlag, Germany (1997)	
	NPL86	BACHARACH-BUHLES, M., et al., "The Effect of Fumaric Acid Esters and Dithranol on Acanthosis and Hyperproliferation in Psoriasis Vulgaris," Acta Derm. Venereol. (Stockh) 76:190-193, Scandinavian University Press, Sweden (1996)	
	NPL87	BALASHOV, K.E., et al., "Increased interleukin 12 production in progressive multiple sclerosis: Induction by activated CD4 <sup>+</sup> T cells via CD40 ligand," <i>Proc. Natl. Acad. Sci. USA 94</i> :599-603, The National Academy of Sciences of the United States of America, United States (1997)	
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	NPL89	BREUER, K., et al., "Therapy of noninfectious granulomatous skin diseases with fumaric acid esters," Br. J. Dermatol. 152:1290-1295, British Association of Dermatologists, England (2005)	
	NPL90	EBERLEIN-KÖNIG, B., et al., "Disseminated Granuloma Annulare - Treatment with Fumaric Acid Esters," <i>Dermatology 210</i> :223-226, S. Karger AG, Switzerland (2005)	

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Art Unit	To be assigned			
Examiner Name	To be assigned			
Attorney Docket Number	2159.3210002/JMC/MRG/U-S			

		NON PATENT LITERATURE DOCUMENTS	
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	NPL91	LINK, H., et al., "Virus-reactive and autoreactive T cells are accumulated in cerebrospinal fluid in multiple sclerosis," <i>J. Neuroimmunol.</i> 38:63-74, Elsevier Science Publishers B.V., Netherlands (1992)	
	NPL92	LITJENS, N.H.R., <i>et al.</i> , "Monomethylfumarate affects polarization of monocytederived dendritic cells resulting in down-regulated Th1 lymphocyte responses," <i>Eur. J. Immunol.</i> 34:565-575, WILEY-VCH Verlag GmbH & Co. KGaA, Germany (2004)	
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	NPL94	LOBELL, A., et al., "Presence of CpG DNA and the Local Cytokine Milieu Determine the Efficacy of Suppressive DNA Vaccination in Experimental Autoimmune Encephalomyelitis," <i>J. Immunol.</i> 163:4754-4762, The American Association of Immunologists, United States (1999)	
	NPL95	LOEWE, R., <i>et al.</i> , "Dimethylfumarate Inhibits TNF-Induced Nuclear Entry of NF-κB/p65 in Human Endothelial Cells," <i>J. Immunol.</i> 168:4781-4787, The American Association of Immunologists, United States (2002)	and the state of t
	NPL96	LUFT, R., "The development of mitochondrial medicine," <i>Proc. Natl. Acad. Sci. USA</i> 91:8731-8738, National Academy of Sciences, United States (1994)	
	NPL97	MAYNE, M., et al., "Antisense Oligodeoxynucleotide Inhibition of Tumor Necrosis Factor-α Expression Is Neuroprotective After Intracerebral Hemorrhage," Stroke 32:240-248, American Heart Association, Inc., United States (2001)	
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	NPL100	MUSIEK, E.S., et al., "Cyclopentenone isoprostanes are novel bioactive products of lipid oxidation which enhance neurodegeneration," <i>J. Neurochem.</i> 97:1301-1313, International Society for Neurochemistry, England (2006)	

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		NON PATENT LITERATURE DOCUMENTS	
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	NPL101	MUSTAFA, M.I., et al., "T cell immunity and interferon-γ secretion during experimental allergic encephalomyelitis in Lewis rats," <i>J. Neuroimmunol.</i> 31:165-177, Elsevier Science Publishers B.V., Netherlands (1991)	
	NPL102	MUSTAFA, M., et al., "Immunopharmacologic Modulation of Experimental Allergic Encephalomyelitis: Low-Dose Cyclosporin-A Treatment Causes Disease Relapse and Increased Systemic T and B Cell-Mediated Myelin-Directed Autoimmunity," Scand. J. Immunol. 38:499-507, Blackwell Scientific Publications, England (1993)	
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	NPL107	NIBBERING, P.H., et al., "Effects of Monomethylfumarate on Human Granulocytes," J. Invest. Dermatol. 101:37-42, The Society for Investigative Dermatology, Inc., United States (1993)	
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	NPL109	NIEBOER, C., et al., "Systemic therapy with fumaric acid derivates: New possibilities in the treatment of psoriasis," J. Am. Acad. Dermatol. 20:601-608, Mosby, United States (1989)	
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		NON PATENT LITERATURE DOCUMENTS	***************************************
Examiner Initials*	appropriate) title of the item (book magazine journal garial exampagium actalog		T <sup>2</sup>
	NPL111	OLSSON, T., et al., "Autoreactive T Lymphocytes in Multiple Sclerosis Determined by Antigen-induced Secretion of Interferon-y," J. Clin. Invest. 86:981-985, The American Society for Clinical Investigation, Inc., United States (1990)	
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	NPL114	OLSSON, T., "Cerebrospinal Fluid," <i>Ann. Neurol. 36</i> :S100-S102, American Neurological Association, United States (1994)	
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	NPL116	OLSSON, T., "Cytokine-producing cells in experimental autoimmune encephalomyelitis and multiple sclerosis," <i>Neurology 45(Suppl 6)</i> :S11-S15, Lipincott Williams & Wilkins, United States (1995)	
	NPL117	OLSSON, T., et al., "Genetics of rat neuroinflammation," J. Neuroimmunol. 107:191-200, Elsevier Science B.V., Netherlands (2000)	***************************************
	NPL118	OLSSON, T., <i>et al.</i> , "Depletion of V $\beta$ 5.2/5.3 T cells with a humanized antibody in patients with multiple sclerosis," <i>Eur. J. Neurol.</i> 9:153-164, European Federation of Neurological Societies, England (2002)	
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	NPL120	PANITCH, H.S., et al., "Exacerbations Of Multiple Sclerosis In Patients Treated With Gamma Interferon," Lancet 329:893-895, Lancet Publishing Group, England (1987)	

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	NPL121	PEREIRA, M.A., et al., "Use of azoxymethane-induced foci of aberrant crypts in rat colon to identify potential cancer chemopreventive agents," <i>Carcinogenesis</i> 15(5):1049-1054, Oxford University Press, England (1994)	
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	NPL124	PROCHASKA, H.J., et al., "Elevation of Glutathione Levels by Phase II Enzyme Inducers: Lack of Inhibition of Human Immunodeficiency Virus Type 1 Replication in Chronically Infected Monocytoid Cells," Mol. Pharmacol. 45:916-921, The American Society for Pharmacology and Experimental Therapeutics, United States (1994)	erooniaana.
	NPL125	RAO, C.V., <i>et al.</i> , "Chemoprevention of Azoxymethane-Induced Colon Cancer by Ascorbylpalmitate, Carbenoxolone, Dimethylfumarate and <i>p</i> -Methoxyphenol in Male F344 Rats," <i>Anticancer Res.</i> 15:1199-1204, Anticancer Research, Greece (1995)	44
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	NPL127	RISTORI, G., et al., "T cell response to myelin basic protein before and after treatment with interferon beta in multiple sclerosis," <i>J. Neuroimmunol.</i> 99:91-96, Elsevier Science B.V., Netherlands (1999)	
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	NPL131	ROMAGNANI, S., "The Th1/Th2 paradigm," <i>Immunol. Today</i> 18(6):263-266, Elsevier Science Ltd., England (1997)	
	NPL132	ROOK, G.A.W., et al., "Bacterial vaccines for the treatment of multiple sclerosis and other autoimmune diseases," <i>Immunol. Today 21(10)</i> :503-508, Elsevier Science Ltd., England (2000)	
	NPL133	SAMOILOVA, E.B., et al., "Experimental Autoimmune Encephalomyelitis in Intercellular Adhesion Molecule-1-Deficient Mice," Cell. Immunol. 190:83-89, Academic Press, United States (1998)	
	NPL134	SEBÖK, B., et al., "Antiproliferative and cytotoxic profiles of antipsoriatic fumaric acid derivatives in keratinocyte cultures," Eur. J. Pharmacol. 270:79-87, Elsevier Science B.V., Netherlands (1994)	
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:	NPL136	SINGH, V.K., et al., "The Paradigm of Th1 and Th2 Cytokines. Its Relevance to Autoimmunity and Allergy," <i>Immunol. Res.</i> 20:147-161, Humana Press Inc., United States (1999)	
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Filing Date	Herewith		
First Named Inventor	Matvey E. LUKASHEV		
Art Unit	To be assigned		
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Attorney Docket Number	2159.3210002/JMC/MRG/U-S		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Cite Initials* No.1		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	$T^2$
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#### FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Attorney Docket Number	2159.3210002/JMC/MRG/U-S		

		NON PATENT LITERATURE DOCUMENTS	
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Non Patent Literature Documents								
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published						
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	NPL181	O'GARRA, A., et al., "CD4 <sup>+</sup> T-cell subsets in autoimmunity," Curr. Opin. Immunol. 9:872-883, Current Biology Ltd., England (1997)	-
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	NPL191	SCHILLING, F. and SCHOPF, R.E., "Adultes Debré-de Toni-Fanconi-Syndrom mit Osteomalazie, erworben durch Langzeittherapie einer Psoriasis mit Fumarsäureester zugleich ein Beitrag zur malazischen Osteoarthropathie," <i>Akt. Rheumatol.</i> 24(6):174-179, Georg Thieme Verlag, Germany (1999) (Abstract Only in English)	Abs
	NPL192	SCHILLING, S., et al., "Fumaric acid esters are effective in chronic experimental autoimmune encephalomyelitis and suppress macrophage infiltration," Clin. Exp. Immunol. 145:101-107, British Society for Immunology, England (2006)	
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Complete if Known				
Application Number	To be assigned			
Filing Date	Herewith			
First Named Inventor	Matvey E. LUKASHEV			
Art Unit	To be assigned			
Examiner Name	To be assigned			
Attorney Docket Number	2159.3210002/JMC/MRG/U-S			

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	$T^2$
:	NPL211	Partial English language translation, 4 pages, of <i>Immunmodulation durch Fumaderm.</i> Das richtungsweisende Konzept, Charite-Berlin Hautklinik Symposium, November 1-3, 1996, p. 1-27	
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	NPL214	BAXTER, A.G., et al., "High And Low Diabetes Incidence Nonobese Diabetic (NOD) Mice: Origins And Characterisation," Autoimmunity 9:61-67, Harwood Academic Publishers GmbH, England (1991)	
	NPL215	BAYARD, W., et al., "Perorale Langzeitbehandlung der Psoriasis mit Fumarsäurederivaten" Hautarzt 38:279-285, Springer-Verlag, Germany (1987) (Abstract Only in English)	Abs.
	NPL216	BEN-NUN, A., et al., "The rapid isolation of clonable antigen-specific T lymphocyte lines capable of mediating autoimmune encephalomyelitis," Eur. J. Immunol. 11:195-199, Verlag Chemie, GmbH, Germany (1981)	
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:	NPL218	DINKOVA-KOSTOVA, A.T., et al., "Potency of Michael reaction acceptors as inducers of enzymes that protect against carcinogenesis depends on their reactivity with sulfhydryl groups," <i>Proc. Natl. Acad. Sci. USA 98(6)</i> :3404-3409, National Academy of Sciences, United States (2001)	
	NPL219	Encyclopedia of Molecular Biology and Molecular Medicine, Meyers, R.A., ed., p. 343, VCH Verlagsgesellschaft mbH, Germany (1996)	
	NPL220	ERCOLINI, A.M. and MILLER, S.D., "Mechanisms of Immunopathology in Murine Models of Central Nervous System Demyelinating Disease," <i>J. Immunol.</i> 176(6):3293-3298, The American Association of Immunologists, Inc., United States (March 2006)	

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Matvey E. LUKASHEV

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Sheet 23 of 30	Attorney Docket Number	2159.3210002/JMC/MRG/U-S

Application Number

First Named Inventor

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		NON PATENT LITERATURE DOCUMENTS	••••••
Examiner Cite Initials* No.		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	$T^2$
	NPL221	EUGSTER, HP., <i>et al.</i> , "Severity of symptoms and demyelination in MOG-induced EAE depends on TNFR1," <i>Eur. J. Immunol.</i> 29:626-632, WILEY-VCH Verlag GmbH, Germany (1999)	
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	NPL225	HABIG, W.H., et al., "Glutathione S-Transferases: The First Enzymatic Step in Mercapturic Acid Formation," J. Biol. Chem. 249(22):7130-7139, The American Society for Biological Chemists, Inc., United States (1974)	
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	NPL227	HARTUNG, HP., et al., "The Role Of Macrophages And Eicosanoids In The Pathogenesis Of Experimental Allergic Neuritis," <i>Brain 111</i> :1039-1059, Oxford University Press, England (1988)	***************************************
	NPL228	HEMMINKI, A., et al., "In Vivo Molecular Chemotherapy and Noninvasive Imaging With an Infectivity-Enhanced Adenovirus," J. Natl. Cancer Inst. 94(10):741-749, Oxford University Press, United States (2002)	
	NPL229	JI, H., et al., "Different modes of pathogenesis in T-cell-dependent autoimmunity: clues from two TCR transgenic systems," <i>Immunol. Rev. 169</i> :139-146, Munksgaard International Publishers, Denmark (1999)	
	NPL230	KAPPOS, L., et al., "Efficacy of a novel oral single-agent Fumarate, BG00012, in patients with relapsing-remitting multiple sclerosis: results of a phase II study," oral presentation on May 30, 2006, at the 16th Meeting of the European Neurological Society, May 27-31, 2006, Lausanne, Switzerland	

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:	NPL231	KAPPOS, L., et al., "Efficacy of a novel oral single-agent fumarate, BG00012, in patients with relapsing-remitting multiple sclerosis: results of a phase 2 study," Abstract O108, Proceedings of the 16th Meeting of the European Neurological Society, May 27-31, 2006, Lausanne, Switzerland (Abstract Only)	Abs.
	NPL232	KAPPOS, L., et al., "The Efficacy of BG00012 in Patients With Relapsing-Remitting Multiple Sclerosis: Subgroup Analyses From the Phase 2b Study," poster from the 60th Annual Meeting of the American Academy of Neurology, April 12-19, 2008, Chicago, IL, United States	
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-	NPL237	LINKER, R.A., et al., "CNTF is a major protective factor in demyelinating CNS disease: A neurotrophic cytokine as modulator in neuroinflammation," <i>Nature Medicine</i> 8(6):620-624, Nature America Inc., United States (2002)	00000000000000000000000000000000000000
:	NPL238	LODIE, T.A., et al., "Systematic Analysis of Reportedly Distinct Populations of Multipotent Bone Marrow-Derived Stem Cells Reveals a Lack of Distinction," <i>Tissue Eng. 8(5):739-751</i> , Mary Ann Liebert, Inc., United States (2002)	
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		NON PATENT LITERATURE DOCUMENTS	
Examiner Cite Initials* No. <sup>1</sup>		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
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	NPL248	PERRELLA, O., et al., "Interleukin-10 and IFN-α in multiple sclerosis: is there a balance?" J. Neurovirol. 3(Suppl 1):P17, Stockton Press, United States (1997) (Abstract Only)	Abs.
·	NPL249	POLMAN, C.H., et al., "Diagnostic Criteria for Multiple Sclerosis: 2005 Revisions to the "McDonald Criteria," Ann. Neurol. 58(6):840-846, Wiley-Liss, Inc., United States (2005)	
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	NPL251	ROIT Γ, I.M., et al., eds., "23.Autoimmunity and Autoimmune Disease," in <i>Immunology</i> , p. 23.1-23.12, Gower Medical Publishing, United States (1985)	The state of the s
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	NPL255	SHI, N., et al., "Brain-specific expression of an exogenous gene after i.v. administration," <i>Proc. Natl. Acad. Sci. USA 98(22)</i> :12754-12759, National Academy of Sciences, United States (2001)	
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	NPL271	Office Action mailed May 21, 2001, in U.S. Application No. 09/743,978, Joshi, R.K., et al., § 371(c) date January 17, 2001 (now U.S. Pat. No. 6,355,676 B1)	
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	NPL281	Office Action mailed September 9, 2008, in U.S. Application No. 11/765,563, Joshi, R.K., et al., filed June 20, 2007 (now U.S. Patent No. 7,612,110 B2)				
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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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FIRST SUPPLEMENTAL				JTAL.	Application Number	To be assigned	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	Herewith		
				First Named Inventor	Matvey E. LUKASHEV		
				Art Unit	To be assigned		
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Sheet	30	of	30		Attorney Docket Number	2159.3210002/JMC/MRG/U-S	

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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>				
	NPL291	Office Action notification date September 9, 2010, in U.S. Application No. 12/405,665, Joshi, R.K., et al., filed March 17, 2009 (now U.S. Patent No. 7,915,310 B2)					
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	NPL293	WALLACE, D.C., "Mitochondrial Diseases in Man and Mouse," <i>Science 283</i> :1482-1488, American Association for the Advancement of Science, United States (1999)	and the second s				
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# FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

	Complete if Known		
	Application Number	To be assigned	
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	First Named Inventor	Matvey E. LUKASHEV	
Art Unit		To be assigned	
	Examiner Name	To be assigned	
	Attorney Docket Number	2159.3210002/JMC/MRG/U-S	

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Examiner initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
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Examiner	Cite No. 1  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication	Name of Patentee or	Pages, Columns, Lines,					
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	Examiner	/John Hlm/	Date	05/02/2012
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FIRST SUPPLEMENTAL	Application Number	To be assigned	
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INFORMATION DISCLOSURE	First Named Inventor	Matvey E. LUKASHEV	
STATEMENT BY APPLICANT	Art Unit	To be assigned	
(Use as many sheets as necessary)	Examiner Name	To be assigned	
Sheet 2 of 7	Attorney Docket Number	2159.3210002/JMC/MRG/U-S	

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Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where			
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Substitute for form 1449/PTO Complete if Known To be assigned **Application Number** FIRST SUPPLEMENTAL Filing Date Herewith INFORMATION DISCLOSURE Matvey E. LUKASHEV First Named Inventor STATEMENT BY APPLICANT Art Unit To be assigned (Use as many sheets as necessary) Examiner Name To be assigned Attorney Docket Number 2159.3210002/JMC/MRG/U-S Sheet 3 of

			U.S. PATEN	T DOCUMENTS	
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Substitute for form 1449/PTO	Com	olete if Known
FIRST SUPPLEMENTAL	Application Number	To be assigned
	Filing Date	Herewith
INFORMATION DISCLOSURE	First Named Inventor	Matvey E. LUKASHEV
STATEMENT BY APPLICANT	Art Unit	To be assigned
(Use as many sheets as necessary)	Examiner Name	To be assigned
Sheet 4 of 7	Attorney Docket Number	2159.3210002/JMC/MRG/U-S

			U.S. PATEN	T DOCUMENTS	
		Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where
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STATEMENT BY APPLICANT	Art Unit	To be assigned
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Sheet 5 of 7	Attorney Docket Number	2159.3210002/JMC/MRG/U-S

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initials*	Cite No. 1	Number-Kind Code <sup>2</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
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Examiner John Ulm/ Date 05/02/2012 Considered

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Examiner initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -  Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
/J.U./	FP49	WO 2006/091428 A2	08-31-2006	Schering Corporation; Pharmacopeia Drug Discovery, Inc.		
/J.U./	FP50	WO 2007/042034 A1	04-19-2007	Aditech Pharma AB		
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FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	To be assigned	
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	First Named Inventor	Matvey E. LUKASHEV	
	Art Unit	To be assigned	
(Use as many sheets as necessary)	Examiner Name	To be assigned	
Sheet 1 of 30	Attorney Docket Number	2159.3210002/JMC/MRG/U-S	
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	NPL1	Thomson Innovation Patent Record, DWPI Accession No. 1979-58797B, English language Abstract of Japanese Patent Publication No. 54-80439 A, (1979)	Abs.
:	NPL2	English language Abstract of German Patent Publication No. DE 38 34 794 A1, European Patent Office, Espacenet database — Worldwide (2001)	Abs.
	NPL3	English language Abstract of Japanese Patent Publication No. JP 6-345644 A, European Patent Office, Espacenet database — Worldwide (2001)	Abs.
	NPL4	English language Abstract of Japanese Patent Publication No. JP 8-99906 A, European Patent Office, Espacenet database — Worldwide (2001)	Abs
	NPL5	English language Abstract of Japanese Patent Publication No. JP 9-221428 A, European Patent Office, Espacenet database — Worldwide (2001)	Abs
	NPL6	English language Abstract of WIPO Patent Publication No. WO 97/48405 A1, European Patent Office, Espacenet database — Worldwide (2001)	Abs
	NPL7	English language Abstract of Russian Patent Publication No. RU 2 189 813 C1, European Patent Office, Espacenet database — Worldwide (2002)	Abs
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	NPL8	English language Abstract of WIPO Patent Publication No. WO 2005/027899 A1, European Patent Office, Espacenet database — Worldwide (2005)	Abs
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FIRST SUPPLEMENTAL	Application Number	To be assigned	
	Filing Date	Herewith	
INFORMATION DISCLOSURE	First Named Inventor	Matvey E. LUKASHEV	
STATEMENT BY APPLICANT	Art Unit	To be assigned	
(Use as many sheets as necessary)	Examiner Name	To be assigned	
Sheet 2 of 30	Attorney Docket Number	2159.3210002/JMC/MRG/U-S	

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:	NPL11	BACHARACH-BUHLES, M., et al., "Fumaric Acid Esters (FAEs) Suppress CD 15-and ODP 4-positive Cells in Psoriasis," Acta. Derm. Venereol. Suppl. (Stockh) 186:79-82, Scandinavian University Press, Norway (1994)	
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****	NPL15	BROWN, T.R. and KRAFT, G.H., "Multiple Sclerosis: A Paradigm Shift," <i>Phys. Med. Rehabil. Clin. N. Am. 16</i> :xvii-xx, Elsevier Inc., United States (2005)	***************************************
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Equivalent of Form PTO/SB/08b (7-09) Substitute for form 1449/PTO Complete if Known Application Number To be assigned FIRST SUPPLEMENTAL Filing Date Herewith INFORMATION DISCLOSURE First Named Inventor Matvey E. LUKASHEV STATEMENT BY APPLICANT Art Unit To be assigned (Use as many sheets as necessary) **Examiner Name** To be assigned Sheet of Attorney Docket Number 2159.3210002/JMC/MRG/U-S

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:	NPL21	DE HAAN, P., "The Risk of Sensibilization and Contact Urticaria upon Topical Application of Fumaric Acid Derivatives," <i>Dermatology 188</i> :126-130, Karger AG, Switzerland (1994)	
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	NPL29	FERBER, I.A., et al., "Mice with a Disrupted IFN-γ Gene Are Susceptible to the Induction of Experimental Autoimmune Encephalomyelitis (EAE)," J. Immunol. 156:5-7, The American Association of Immunologists, United States (1996)	
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Signature	/John Ulm/	Considered	05/02/2012

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449/PTO	Complete if Known		
FIRST SUPPLEMENTAL	Application Number	To be assigned	
	Filing Date	Herewith	
INFORMATION DISCLOSURE	First Named Inventor	Matvey E. LUKASHEV	
STATEMENT BY APPLICANT	Art Unit	To be assigned	
(Use as many sheets as necessary)	Examiner Name	To be assigned	
Sheet 4 of 30	Attorney Docket Number	2159.3210002/JMC/MRG/U-S	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	$T^2$
:	NPL31	FLIEGNER, L. and SPIEGEL, P., "Osteomalazie als offenbar seltene Nebenwirkung der oralen Fumarsäuretherapie," <i>Hautarzt 43</i> :554-560, Springer-Verlag, Germany (1992) (Abstract Only in English)	Abs.
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Examiner	/John Úlm/	***************************************	Date	05/02/2012
Signature			Considered	

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FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application Number To be assigned Filing Date Herewith First Named Inventor Matvey E. LUKASHEV Art Unit To be assigned Examiner Name To be assigned Attorney Docket Number 2159.3210002/JMC/MRG/U-S

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		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	NPL41	GIOVANNONI, G. and MILLER, D.H., "Multiple sclerosis and its treatment," J. R. Coll. Physicians Lond. 33(4):315-322, Royal College of Physicians, England (1999)	
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	NPL51	ISSAZADEH, S., <i>et al.</i> , "Cytokines in relapsing experimental autoimmune encephalomyelitis in DA rats: persistent mRNA expression of proinflammatory cytokines and absent expression of interleukin-10 and transforming growth factor-β," <i>J. Neuroimmunol.</i> 69:103-115, Elsevier Science B.V., Netherlands (1996)	
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	NPL56	KHADEMI, M., et al., "T Cell Ig- and Mucin-Domain-Containing Molecule-3 (TIM-3) and TIM-1 Molecules Are Differentially Expressed on Human Th1 and Th2 Cells and in Cerebrospinal Fluid-Derived Mononuclear Cells in Multiple Sclerosis," <i>J. Immunol.</i> 172:7169-7176, The American Association of Immunologists, Inc., United States (2004)	
	NPL57	KIEHL, R. and IONESCU, G., "A Defective Purine Nucleotide Synthesis Pathway in Psoriatic Patients," <i>Acta Derm. Venereol. (Stockh)</i> 72:253-255, Society for the Publication of Acta Dermato-Venerologica, Sweden (1992)	
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	NPL61	KRAKOWSKI, M. and OWENS, T., "Interferon-γ confers resistance to experimental allergic encephalomyelitis," <i>Eur. J. Immunol.</i> 26:1641-1646, VCH Verlagsgesellschaft mbH, Germany (1996)	,,,,,,,,,	
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Equivalent of Form PTO/SB/08b (7-09) Substitute for form 1449/PTO Complete if Known Application Number To be assigned FIRST SUPPLEMENTAL Filing Date Herewith INFORMATION DISCLOSURE First Named Inventor Matvey E. LUKASHEV STATEMENT BY APPLICANT Art Unit To be assigned (Use as many sheets as necessary). Examiner Name To be assigned Sheet of Attorney Docket Number 2159,3210002/JMC/MRG/U-S

		NON PATENT LITERATURE DOCUMENTS	
Examiner Cite Initials* No. <sup>1</sup>		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T
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INFORMATION DISCLOSURE	First Named Inventor	Matvey E. LUKASHEV
STATEMENT BY APPLICANT	Art Unit	To be assigned
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Sheet 9 of 30	Attorney Docket Number	2159.3210002/JMC/MRG/U-S

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	NPL101	MUSTAFA, M.I., et al., "T cell immunity and interferon-γ secretion during experimental allergic encephalomyelitis in Lewis rats," <i>J. Neuroimmunol.</i> 31:165-177, Elsevier Science Publishers B.V., Netherlands (1991)		
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:	NPL111	OLSSON, T., et al., "Autoreactive T Lymphocytes in Multiple Sclerosis Determined by Antigen-induced Secretion of Interferon-γ," J. Clin. Invest. 86:981-985, The American Society for Clinical Investigation, Inc., United States (1990)	7)))))))	
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FIRST SUPPLEMENTAL	Application Number	To be assigned		
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INFORMATION DISCLOSURE	First Named Inventor	Matvey E. LUKASHEV		
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	NPL121	PEREIRA, M.A., et al., "Use of azoxymethane-induced foci of aberrant crypts in rat colon to identify potential cancer chemopreventive agents," <i>Carcinogenesis</i> 15(5):1049-1054, Oxford University Press, England (1994)		
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000000000000000000000000000000000000000	NPLT23	type 1 replication, <i>Proc. Wall. Acad. Sci. US/1 90:3953-3957</i> , National Academy of Sciences, United States	00000000	
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	NPL141	SU, J.Y.C., <i>et al.</i> , "Reduction of H <sub>2</sub> O <sub>2</sub> -evoked, intracellular calcium increases in the rat N18-RE-105 neuronal cell line by pretreatment with an electrophilic antioxidant inducer," <i>Neurosci. Lett.</i> 273:109-112, Elsevier Science Ireland Ltd., Ireland (1999)		
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	NPL150	ZHU, J., et al., "Cytokine production and the pathogenesis of experimental autoimmune neuritis and Guillain-Barré syndrome," <i>J. Neuroimmunol.</i> 84:40-52, Elsevier Science B.V., Netherlands (1998)		

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	First Named Inventor	Matvey E. LUKASHEV	
STATEMENT BY APPLICANT	Art Unit	To be assigned	
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Sheet 16 of 30	Attorney Docket Number	2159.3210002/JMC/MRG/U-S	

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>	
	NPL151	ZIPP, F., "No Evidence for Generation of Th-2-like MBP-Specific T-Cell Lines by Blockade of the Costimulatory Molecule B7-1," <i>Scand. J. Immunol.</i> 52:510-514, Blackwell Science Ltd., England (2000)		
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	NPL159	GAMBICHLER, T., et al., "Clearance of Necrobiosis lipoidica with Fumaric Acid Esters," <i>Dermatology</i> 207(4):422-424, S. Karger AG, Switzerland (2003)		
	NPL160	GAO, L., et al., "Novel N-3 Fatty Acid Oxidation Products Activate Nrf2 By Destabilizing The Association Between Keap1 and Cullin3," <i>J. Biol. Chem. M607622200</i> , 18 pages, The American Society for Biochemistry and Molecular Biology, Inc., United States (November 2006)		

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:	NPL161	GILGUN-SHERKI, Y., et al., "The role of oxidative stress in the pathogensis of multiple sclerosis: The need for effective antioxidant therapy," J. Neurol. 251:261-268, Springer-Verlag, Germany (2004)	
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	NPL171	LAHTI, A., et al., "Acetylsalicylic acid inhibits non-immunologic contact urticaria,"  Contact Dermatitis 16:133-135, Munksgaard International Publishers Ltd., Denmark  (1987)	
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	NPL181	O'GARRA, A., et al., "CD4 <sup>+</sup> T-cell subsets in autoimmunity," Curr. Opin. Immunol. 9:872-883, Current Biology Ltd., England (1997)	:
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	NPL192	SCHILLING, S., et al., "Fumaric acid esters are effective in chronic experimental autoimmune encephalomyelitis and suppress macrophage infiltration," <i>Clin. Exp. Immunol.</i> 145:101-107, British Society for Immunology, England (2006)	
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:	NPL201	WAKABAYASHI, N., et al., "Keap1-null mutation leads to postnatal lethality due to constitutive Nrf2 activation," Nat. Genet. 35(3):238-245, Nature Publishing Group, United States (2003)	:
	NPL202	WANSCHER, B. and SØRENSEN, P.S., "Nye behandlingsmuligheder for dissemineret sklerose?" <i>Ugeskr Læger 156(43)</i> :6353-6358, Den Alm Danske Laegerforening, Denmark (1994) (Abstract Only in English)	Abs.
:	NPL203	WERDENBERG, D., et al., "Presystemic Metabolism and Intestinal Absorption of Antipsoriatic Fumaric Acid Esters," <i>Biopharm. Drug Dispos.</i> 24(6):259-273, John Wiley & Sons, Ltd., England (2003)	
,	NPL204	WERDENBERG, D., Stability, Permeability and Pharmacokinetics of Perorally Administered Fumarates, Doctoral Dissertation submitted to the Swiss Federal Institute of Technology Zurich, pp. 86, 87, 90, 125 (2003)	
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	NPL209	"Polyarthritis," Wikipedia.org, accessed at <a href="https://www.en.wikipedia.org/wiki/Polyarthritis">www.en.wikipedia.org/wiki/Polyarthritis</a> , accessed on September 3, 2008, 4 pages	
	NPL210	Immunmodulation durch Fumaderm. Das richtungsweisende Konzept, Charite-Berlin Hautklinik Symposium, November 1-3, 1996, p. 1-27	

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- 1	Signature	/John Ulm/	Considered	05/02/2012

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Application Number	To be assigned	
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First Named Inventor	Matvey E. LUKASHEV	
Art Unit	To be assigned	
Examiner Name	To be assigned	
Attorney Docket Number	2159.3210002/JMC/MRG/U-S	

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Examiner Cite Initials* No. <sup>1</sup>		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
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		NON PATENT LITERATURE DOCUMENTS	
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	NPL281	Office Action mailed September 9, 2008, in U.S. Application No. 11/765,563, Joshi, R.K., et al., filed June 20, 2007 (now U.S. Patent No. 7,612,110 B2)			
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,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	NPL283	Office Action mailed December 14, 2007, in U.S. Application No. 11/765,578, Joshi, R.K., et al., filed June 20, 2007 (now U.S. Patent No. 7,619,001 B2)			
···	NPL284	Office Action mailed July 25, 2008, in U.S. Application No. 11/765,578, Joshi, R.K., et al., filed June 20, 2007 (now U.S. Patent No. 7,619,001 B2)			
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	NPL288	Office Action notification date January 19, 2010, in U.S. Application No. 12/405,661, Joshi, R.K., et al., filed March 17, 2009 (now U.S. Patent No. 7,803,840 B2)			
	NPL289	Office Action notification date May 20, 2010, in U.S. Application No. 12/405,661, Joshi, R.K., et al., filed March 17, 2009 (now U.S. Patent No. 7,803,840 B2)			
	NPL290	Office Action notification date March 23, 2010, in U.S. Application No. 12/405,665, Joshi, R.K., et al., filed March 17, 2009 (now U.S. Patent No. 7,915,310 B2)			

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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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## ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.U./

Equivalent of Form PTO/SB/08b (7-09) Substitute for form 1449/PTO Complete if Known Application Number To be assigned FIRST SUPPLEMENTAL Filing Date Herewith INFORMATION DISCLOSURE Matvey E. LUKASHEV First Named Inventor STATEMENT BY APPLICANT Art Unit To be assigned To be assigned (Use as many sheets as necessary) Examiner Name 2159.3210002/JMC/MRG/U-S Attorney Docket Number 30 of 30 Sheet

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	NPL291	Office Action notification date September 9, 2010, in U.S. Application No. 12/405,665, Joshi, R.K., et al., filed March 17, 2009 (now U.S. Patent No. 7,915,310 B2)	
00000000000000000000000000000000000000	NPL292	English language Abstract of Chinese Patent Publication No. CN 1125141 A.  European Patent Office, Espacenet database — Worldwide (Abstract Only)	Abs
	NPL293	WALLACE, D.C., "Mitochondrial Diseases in Man and Mouse," <i>Science 283</i> :1482-1488, American Association for the Advancement of Science, United States (1999)	

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