



TTAB

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Harvey Freedenberg
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September 21, 2012

United States Patent and Trademark Office
Trademark Trial and Appeal Board
Attention: Commissioner for Trademarks
P.O. Box 1451
Alexandria, VA 22313-1451

RE: Mylan, Inc., Opposer v.
Beaufort County Allergy, Applicant
Opposition No. 91195868

Dear Commissioner:

Enclosed for filing please find Opposer Mylan, Inc.'s Notice of Reliance regarding the above-referenced opposition proceeding.

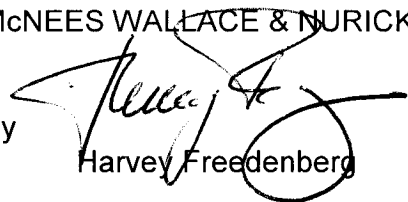
We simultaneously are serving copies of all of the materials filed herewith upon counsel for Applicant.

Thank you for your attention to this filing request.

Sincerely,

McNEES WALLACE & NURICK LLC

By


Harvey Freedenberg

HF:jh
Enclosures
c: Anthony Verna III, Esquire (w/encl.)



09-21-2012

U.S. Patent and Trademark Office #72

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United States Patent and Trademark Office
Trademark Trial and Appeal Board
Commissioner for Trademarks
September 21, 2012
Page 2

bc: Lisa Pessa, Esquire (w/encl.)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD**

MYLAN, INC.,	:	
Opposer,	:	
	:	
v.	:	Opposition No. 91195868
	:	
BEAUFORT COUNTY ALLERGY,	:	
Applicant.	:	

OPPOSER MYLAN, INC.'S NOTICE OF RELIANCE

Opposer Mylan, Inc. ("Mylan") notifies the Trademark Trial and Appeal Board and Applicant Beaufort County Allergy ("Beaufort") of its intent to rely upon the following materials in the above-captioned proceeding. Copies of said materials are attached hereto and filed of record:

1. Printouts of information from the electronic database records of the USPTO showing the current status and title of the following registrations to establish the priority of Mylan's EPIPEN and EPI marks and to establish the existence of a family of said marks:

a. Mylan's federal trademark registration for the mark EPIPEN, Registration No. 1,124,454. See Exhibit 1.

b. Mylan's federal trademark registration for the mark EPIPEN, Registration No. 1,479,294. See Exhibit 2.

c. Mylan's federal trademark registration for the mark EPIPEN JR. 2-PAK, Registration No. 2,576,013. See Exhibit 3.

d. Mylan's federal trademark registration for the mark EPIPEN 2-PAK, Registration No. 2,576,014. See Exhibit 4.

e. Mylan's federal trademark application for the mark EPIPEN-READY, Serial No. 77/919,265. See Exhibit 5.

f. Mylan's federal trademark application for the mark EPIPEN PREPARED, Serial No. 77/919,257. See Exhibit 6.

g. Mylan's federal trademark application for the mark EPIPEN PREPARED, Serial No. 77/919,269. See Exhibit 7.

h. Mylan's federal trademark application for the mark EPI-SET, Serial No. 77/919,271. See Exhibit 8.

i. Mylan's federal trademark application for the mark EPICARD, Serial No. 77/927,738. See Exhibit 9.

2. Excerpts from the discovery deposition of Thomas C. Beller, M.D., taken on February 13, 2012. See Exhibit 10. The Board's attention is directed specifically to the listed pages of Dr. Beller's deposition that are relevant to the following issues:

a. Identical nature of Mylan's and Beaufort's goods (pp. 20-21).

b. Competitive nature of Mylan's and Beaufort's goods (pp. 30-31; 67).

c. Recognition of EPIPEN® as a brand name (pp. 29-31).

d. Recognition of the importance of training patients in the proper use of a prescribed autoinjector (pp. 63-64).

e. Market share of EPIPEN® autoinjector (p. 66).

f. Consumers and channels of trade for Beaufort's autoinjector device (p. 105).

3. Internet Materials consisting of dictionary and other references to the term EPIPEN® that reflect its recognition as a brand name and support Mylan's contention that the mark has become famous:

a. American Heritage Medical Dictionary (definition of "EPIPEN®"). See Exhibit 11.

b. Oxfordreference.com (definition of "adrenaline"). See Exhibit 12.

c. Oxfordreference.com (definition of "EPIPEN®"). See Exhibit 13.

d. Wikipedia (entry for "Epinephrine autoinjector"). See Exhibit 14.

e. Oxford English Dictionary (definition of "EPIPEN®"). See Exhibit 15.

f. Consumer Health Complete (entry for "Epinephrine") See Exhibit 16.

g. Consumer Health Complete (entry for "EPIPEN®"). See Exhibit 17.

h. "Epinephrine Auto-injectors – Patients May Need Retraining," Website of The Food Allergy & Anaphylaxis Network, May 24, 2010. See Exhibit 18.

i. "When is an Epi-Pen Not an Epi-Pen?" About.Com, June 24, 2010. See Exhibit 19.

j. "Teen Dies After Eating Cooking Containing Peanut," Atlanta Journal-Constitution, August 18, 2011. See Exhibit 20.

k. "Food Allergies Can be Deadly," Atlanta Journal-Constitution, August 19, 2011. See Exhibit 21.

4. Expert reports from the following physicians to refute Beaufort's claim that the term "EpiPen" has become generic for epinephrine autoinjectors and to support Mylan's contention that the mark has become famous:

- a. Ray S. Davis, M.D. See Exhibit 22.
- b. Phil Lieberman, M.D. See Exhibit 23.
- c. Martha V. White, M.D. See Exhibit 24.
- d. Myron Zitt, M.D. See Exhibit 25.
- e. Kevin R. Murphy, M.D. See Exhibit 26.

5. Trademark Trial and Appeal Board docket entries in the following opposition and cancellation proceedings to establish that Mylan has vigorously protected its rights in its EPIPEN® mark. Except as described in Paragraph 6, below, all of these proceedings ended either with cancellation of an existing registration or abandonment of a pending application:

- a. Mylan, Inc. v. Brian Klughaupt Kaplan, Cancellation No. 92051946 (EPIDRYL). See Exhibit 27.
- b. Mylan, Inc. v. Intelliject, Inc., Cancellation No. 92051951 (EPICARD). See Exhibit 28.
- c. Mylan, Inc. v. Teva Pharmaceuticals USA, Inc., Opposition No. 91194703 (EPINOW and EPIZIP). See Exhibit 29.
- d. Mylan, Inc. v. Brian K. Kaplan, Opposition No. 91199177. See Exhibit 30 (EPIDRYL).

e. Mylan, Inc. v. Pernix Therapeutics, Opposition No. 91202308. See Exhibit 31 (EPI-TWIN).

f. Mylan, Inc. v. Osagie O. Imasogie, Opposition No. 91202440. See Exhibit 32 (EPIDRYL).

g. Mylan, Inc. v. Epimed International, Inc., Opposition No. 91204718 (EPIMED). See Exhibit 33.

6. Stipulated Motion to Amend Identification of Goods in Application Serial Nos. 85/328,059 and 85/328,075. See Exhibit 34. In the opposition proceeding identified in Paragraph 5.g., above, the applicant agreed to amend its identification of goods to specifically exclude "prefilled epinephrine auto-injectors and syringes."

7. Applicant's Answers to Opposer's First Set of Interrogatories. See Exhibit 35. The Answers are offered to establish the following matters:

- a. Territorial scope of Applicant's intended use of its mark (No. 4(d)).
- b. Proposed channels of trade of products sold under Applicant's mark (No. 7).

McNEES WALLACE & NURICK LLC

By: /s/ Harvey Freedenberg
Harvey Freedenberg
hfreeden@mwn.com
100 Pine Street
P.O. Box 1166
Harrisburg, PA 17108-1166
Phone: 717-232-8000
Facsimile: 717-237-5300

Attorneys for Opposer
Mylan, Inc.

Dated: September 21, 2012

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this date a true and correct copy of the foregoing **OPPOSER MYLAN, INC.'S NOTICE OF RELIANCE** was served by first class mail upon the following:

Anthony Verna III, Esquire
Kravitz & Verna LLC
160 West End Avenue
New York, NY 10023
averna@kravitzverna.com

/s/ Harvey Freedenberg _____
Harvey Freedenberg

Of Counsel for Opposer
Mylan, Inc.

Dated: September 21, 2012

EXHIBIT 1

Generated on: This page was generated by TSDR on 2012-09-04 9:39:51 EST

Mark: EIPEN

EIPEN

US Serial Number: 73183957 **Application Filing Date:** Aug. 30, 1978
US Registration Number: 1124454 **Registration Date:** Aug. 28, 1979
Register: Principal
Mark Type: Trademark
Status: The registration has been renewed.
Status Date: Dec. 01, 2008

Mark Information

Mark Literal Elements: EIPEN
Standard Character Claim: No
Mark Drawing Type: 1 - TYPESET WORD(S) /LETTER(S) /NUMBER(S)

Goods and Services

Note:

The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [...] indicate deleted goods/services;
- Double parenthesis ((.)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks *.* identify additional (new) wording in the goods/services.

For: HYPODERMIC INJECTORS
International Class: 010 - Primary Class **U.S Class:** 044
Class Status: ACTIVE

Basis: 1(a)
First Use: Aug. 17, 1978 **Use in Commerce:** Aug. 17, 1978

Basis Information (Case Level)

Filed Use:	Yes	Currently Use:	Yes	Amended Use:	No
Filed ITU:	No	Currently ITU:	No	Amended ITU:	No
Filed 44D:	No	Currently 44D:	No	Amended 44D:	No
Filed 44E:	No	Currently 44E:	No	Amended 44E:	No
Filed 66A:	No	Currently 66A:	No		
Filed No Basis:	No	Currently No Basis:	No		

Current Owner(s) Information

Owner Name: Mylan Inc.
1500 Corporate Drive Suite 400
Owner Address: Canonsburg, PENNSYLVANIA 15317
UNITED STATES

Legal Entity Type: CORPORATION **State or Country Where Organized:** PENNSYLVANIA

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Michael A. Doctrow **Docket Number:** 24406-0007

Correspondent

Correspondent Name/Address: Michael A. Doctrow
McNees Wallace & Nurick
100 Pine Street
Harrisburg, PENNSYLVANIA 17108
UNITED STATES

Phone: 717-232-8000 **Fax:** 717-237-5300

Correspondent e-mail: trademarks@mwn.com **Correspondent e-mail Authorized:** Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
Feb. 01, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 04, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 04, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Dec. 07, 2011	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Dec. 01, 2008	REGISTERED AND RENEWED (SECOND RENEWAL - 10 YRS)	68973
Dec. 01, 2008	REGISTERED - SEC. 8 (10-YR) ACCEPTED/SEC. 9 GRANTED	
Dec. 01, 2008	ASSIGNED TO PARALEGAL	68973
Nov. 04, 2008	TEAS SECTION 8 & 9 RECEIVED	
May 07, 2008	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 22, 2008	CASE FILE IN TICRS	
Mar. 15, 2000	REGISTERED AND RENEWED (FIRST RENEWAL - 10 YRS)	
Mar. 15, 2000	REGISTERED - SEC. 9 GRANTED/CHECK RECORD FOR SEC. 8	
Oct. 18, 1999	REGISTERED - COMBINED SECTION 8 (10-YR) & SEC. 9 FILED	
Oct. 18, 1999	REGISTERED - COMBINED SECTION 8 (10-YR) & SEC. 9 FILED	
Aug. 18, 1999	REGISTERED - SEC. 9 FILED/CHECK RECORD FOR SEC. 8	
Dec. 23, 1985	REGISTERED - SEC. 8 (6-YR) ACCEPTED & SEC. 15 ACK.	
Nov. 18, 1985	POST REGISTRATION ACTION MAILED - SEC. 8 & 15	
Aug. 22, 1985	REGISTERED - SEC. 8 (6-YR) & SEC. 15 FILED	

Maintenance Filings or Post Registration Information

Affidavit of Continued Use: Section 8 - Accepted
Affidavit of Incontestability: Section 15 - Accepted
Renewal Date: Aug. 28, 2009

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location: POST REGISTRATION **Date in Location:** Dec. 01, 2008

Assignment Abstract of Title Information

Summary

Total Assignments: 5 **Registrant:** SURVIVAL TECHNOLOGY, INC.

Assignment 1 of 5

Conveyance: ASSIGNS THE ENTIRE INTEREST AND THE GOODWILL

Reel/Frame: 0381/0538 **Pages:** 3

Date Recorded: Dec. 18, 1980

Supporting Documents: No Supporting Documents

Assignor

Name: SURVIVAL TECHNOLOGY, INC. **Execution Date:** Dec. 05, 1980

Legal Entity Type: UNKNOWN **State or Country Where Organized:** No Place Where Organized Found

Assignee

Name: EM INDUSTRIES, INCORPORATED

Legal Entity Type: CORPORATION **State or Country Where Organized:** NEW YORK

Address: 500 EXECUTIVE BLVD.
ELMSFORD, NEW YORK 10523

Correspondent

Correspondent Name: STEPHENS AND BUDERWITZ

Correspondent Address: NORTHCOURT BLDG.
WHITE PLAINS, NY 10601

Domestic Representative - Not Found

Assignment 2 of 5

Conveyance: CHANGE OF NAME

Reel/Frame: 2560/0677 **Pages:** 3

Date Recorded: Aug. 19, 2002

Supporting Documents: assignment-tm-2560-0677.pdf

Assignor

Name: EM INDUSTRIES,
INCORPORATED

Execution Date: Jun. 27, 2002

Legal Entity Type: CORPORATION

State or Country Where Organized: No Place Where Organized Found

Assignee

Name: EMD CHEMICALS INC.

Legal Entity Type: CORPORATION

State or Country Where Organized: NEW YORK

Address: 480 S. DEMOCRAT ROAD
GIBBSTOWN, NEW JERSEY 08027

Correspondent

Correspondent Name: EMD CHEMICALS INC.

Correspondent Address: SUSANNE F. DEAL, ESQ.
480 S. DEMOCRAT ROAD
GIBBSTOWN, NJ 06027

Domestic Representative - Not Found

Assignment 3 of 5

Conveyance: ASSIGNS THE ENTIRE INTEREST

Reel/Frame: 3772/0028 **Pages:** 10

Date Recorded: May 06, 2008

Supporting Documents: assignment-tm-3772-0028.pdf

Assignor

Name: EMD CHEMICALS, INC. **Execution Date:** Oct. 02, 2007
Legal Entity Type: CORPORATION **State or Country Where Organized:** NEW YORK

Assignee

Name: MYLAN LABORATORIES, INC.
Legal Entity Type: CORPORATION **State or Country Where Organized:** PENNSYLVANIA

Address: 1500 CORPORATE DRIVE
SUITE 400
CANONSBURG, PENNSYLVANIA 15317

Correspondent

Correspondent Name: SUE HEBERLIG
Correspondent Address: 100 PINE STREET
HARRISBURG, PA 17108

Domestic Representative - Not Found

Assignment 4 of 5

Conveyance: CHANGE OF NAME
Reel/Frame: 3772/0082 **Pages:** 7
Date Recorded: May 06, 2008
Supporting Documents: assignment-tm-3772-0082.pdf

Assignor

Name: MYLAN LABORATORIES, INC. **Execution Date:** Oct. 02, 2007
Legal Entity Type: CORPORATION **State or Country Where Organized:** PENNSYLVANIA

Assignee

Name: MYLAN INC.
Legal Entity Type: CORPORATION **State or Country Where Organized:** PENNSYLVANIA

Address: 1500 CORPORATE DRIVE
SUITE 400
CANONSBURG, PENNSYLVANIA 15317

Correspondent

Correspondent Name: SUE HEBERLIG

Correspondent Address: 100 PINE STREET
HARRISBURG, PA 17108

Domestic Representative - Not Found

Assignment 5 of 5

Conveyance: SECURITY AGREEMENT

Reel/Frame: 4704/0376 **Pages:** 26

Date Recorded: Nov. 21, 2011

Supporting Documents: assignment-tm-4704-0376.pdf

Assignor

Name: DEY PHARMA, L.P. **Execution Date:** Nov. 14, 2011
Legal Entity Type: LIMITED PARTNERSHIP **State or Country Where Organized:** DELAWARE

Name: MYLAN INSTITUTIONAL INC., (F/K/A UDL LABORATORIES, INC.) **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** ILLINOIS

Name: MYLAN PHARMACEUTICALS, INC. **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** WEST VIRGINIA

Name: MYLAN BERTEK PHARMACEUTICALS INC. (F/K/A BERTEK PHARMACEUTICALS, INC.) **Execution Date:** Nov. 14, 2011

Legal Entity Type: CORPORATION
State or Country Where Organized: TEXAS

Name: MYLAN INC. (F/K/A MYLAN LABORATORIES INC.) **Execution Date:** Nov. 14, 2011

Legal Entity Type: CORPORATION
State or Country Where Organized: PENNSYLVANIA

Name: SOMERSET PHARMACEUTICALS, INC. **Execution Date:** Nov. 14, 2011

Legal Entity Type: CORPORATION
State or Country Where Organized: DELAWARE

Name: MYLAN TECHNOLOGIES, INC. **Execution Date:** Nov. 14, 2011

Legal Entity Type: CORPORATION
State or Country Where Organized: WEST VIRGINIA

Assignee

Name: BANK OF AMERICA, N.A., AS ADMINISTRATIVE AGENT

Legal Entity Type: ASSOCIATION
State or Country Where Organized: UNITED STATES

Address: 101 N TRYON STREET, NC1-001-05-45
ONE INDEPENDENCE CENTER
CHARLOTTE, NORTH CAROLINA USA 28255-0001

Correspondent

Correspondent Name: MICHAEL VIOLET

Correspondent Address: CT LIEN SOLUTIONS
4400 EASTON COMMONS WAY, SUITE 125
COLUMBUS, OH 43219

Domestic Representative - Not Found

EXHIBIT 2

Generated on: This page was generated by TSDR on 2012-09-04 10:01:19 EST
Mark: EIPEN
US Serial Number: 73666943 **Application Filing Date:** Jun. 18, 1987
US Registration Number: 1479294 **Registration Date:** Mar. 08, 1988
Register: Principal
Mark Type: Trademark
Status: The registration has been renewed.
Status Date: Jul. 30, 2008
Publication Date: Dec. 15, 1987

Mark Information

Mark Literal Elements: EIPEN
Standard Character Claim: No
Mark Drawing Type: 1 - TYPESET WORD(S) /LETTER(S) /NUMBER(S)

Related Properties Information

Claimed Ownership of US Registrations: 1124454, and others

Goods and Services

Note:

The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [...] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks *..* identify additional (new) wording in the goods/services.

For: INJECTABLE PHARMACEUTICALS FOR TREATMENT OF ANAPHYLACTIC REACTIONS TO INSECT STINGS

International Class: 005 - Primary Class **U.S Class:** 018
Class Status: ACTIVE
Basis: 1(a)
First Use: Aug. 17, 1978 **Use in Commerce:** Aug. 17, 1978

Basis Information (Case Level)

Filed Use:	Yes	Currently Use:	Yes	Amended Use:	No
Filed ITU:	No	Currently ITU:	No	Amended ITU:	No
Filed 44D:	No	Currently 44D:	No	Amended 44D:	No
Filed 44E:	No	Currently 44E:	No	Amended 44E:	No
Filed 66A:	No	Currently 66A:	No		
Filed No Basis:	No	Currently No Basis:	No		

Current Owner(s) Information

Owner Name: MYLAN INC.
SUITE 400
Owner Address: 1500 CORPOATE DRIVE
CANONSBURG, PENNSYLVANIA 15317
UNITED STATES

Legal Entity Type: CORPORATION **State or Country Where Organized:** PENNSYLVANIA

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Michael A. Doctrow

Correspondent

Correspondent Name/Address: Michael A. Doctrow
McNees Wallace & Nurick
100 Pine Street
Harrisburg, PENNSYLVANIA 17108
UNITED STATES

Phone: 717-232-8000

Fax: 717-237-5300

Correspondent e-mail: trademarks@mwn.com

Correspondent e-mail Authorized: Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
Feb. 01, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 04, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 04, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Dec. 07, 2011	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jul. 30, 2008	REGISTERED AND RENEWED (FIRST RENEWAL - 10 YRS)	60132
Jul. 30, 2008	REGISTERED - SEC. 8 (10-YR) ACCEPTED/SEC. 9 GRANTED	
Jul. 22, 2008	ASSIGNED TO PARALEGAL	60132
Jul. 10, 2008	TEAS SECTION 8 & 9 RECEIVED	
May 07, 2008	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Apr. 30, 2007	CASE FILE IN TICRS	
Jun. 21, 1994	REGISTERED - SEC. 8 (6-YR) ACCEPTED & SEC. 15 ACK.	
Mar. 01, 1994	REGISTERED - SEC. 8 (6-YR) & SEC. 15 FILED	
Mar. 08, 1988	REGISTERED-PRINCIPAL REGISTER	
Dec. 15, 1987	PUBLISHED FOR OPPOSITION	
Nov. 13, 1987	NOTICE OF PUBLICATION	
Oct. 15, 1987	APPROVED FOR PUB - PRINCIPAL REGISTER	
Sep. 28, 1987	CORRESPONDENCE RECEIVED IN LAW OFFICE	
Sep. 10, 1987	NON-FINAL ACTION MAILED	
Sep. 03, 1987	ASSIGNED TO EXAMINER	61700

Maintenance Filings or Post Registration Information

Affidavit of Continued Use: Section 8 - Accepted

Affidavit of Incontestability: Section 15 - Accepted

Renewal Date: Mar. 08, 2008

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location: POST REGISTRATION

Date in Location: Jul. 30, 2008

Assignment Abstract of Title Information

Summary

Total Assignments: 4

Registrant: EM INDUSTRIES, INC.

Assignment 1 of 4

Conveyance: CHANGE OF NAME

Reel/Frame: 2560/0677

Pages: 3

Date Recorded: Aug. 19, 2002

Supporting Documents: assignment-tm-2560-0677.pdf

Assignor

Name: EM INDUSTRIES, INCORPORATED

Execution Date: Jun. 27, 2002

Legal Entity Type: CORPORATION

State or Country Where Organized: No Place Where Organized Found

Assignee

Name: EMD CHEMICALS INC.

Legal Entity Type: CORPORATION

State or Country Where Organized: NEW YORK

Address: 480 S. DEMOCRAT ROAD
GIBBSTOWN, NEW JERSEY 08027

Correspondent

Correspondent Name: EMD CHEMICALS INC.

Correspondent Address: SUSANNE F. DEAL, ESQ.
480 S. DEMOCRAT ROAD
GIBBSTOWN, NJ 06027

Domestic Representative - Not Found

Assignment 2 of 4

Conveyance: ASSIGNS THE ENTIRE INTEREST

Reel/Frame: 3772/0028 **Pages:** 10

Date Recorded: May 06, 2008

Supporting Documents: assignment-tm-3772-0028.pdf

Assignor

Name: EMD CHEMICALS, INC. **Execution Date:** Oct. 02, 2007

Legal Entity Type: CORPORATION **State or Country Where Organized:** NEW YORK

Assignee

Name: MYLAN LABORATORIES, INC.

Legal Entity Type: CORPORATION **State or Country Where Organized:** PENNSYLVANIA

Address: 1500 CORPORATE DRIVE
SUITE 400
CANONSBURG, PENNSYLVANIA 15317

Correspondent

Correspondent Name: SUE HEBERLIG

Correspondent Address: 100 PINE STREET
HARRISBURG, PA 17108

Domestic Representative - Not Found

Assignment 3 of 4

Conveyance: CHANGE OF NAME

Reel/Frame: 3772/0082 **Pages:** 7

Date Recorded: May 06, 2008

Supporting Documents: [assignment-tm-3772-0082.pdf](#)

Assignor

Name: MYLAN LABORATORIES, INC. **Execution Date:** Oct. 02, 2007

Legal Entity Type: CORPORATION **State or Country Where Organized:** PENNSYLVANIA

Assignee

Name: MYLAN INC.

Legal Entity Type: CORPORATION **State or Country Where Organized:** PENNSYLVANIA

Address: 1500 CORPORATE DRIVE
SUITE 400
CANONSBURG, PENNSYLVANIA 15317

Correspondent

Correspondent Name: SUE HEBERLIG

Correspondent Address: 100 PINE STREET
HARRISBURG, PA 17108

Domestic Representative - Not Found

Assignment 4 of 4

Conveyance: SECURITY AGREEMENT

Reel/Frame: [4704/0376](#) **Pages:** 26

Date Recorded: Nov. 21, 2011

Supporting Documents: [assignment-tm-4704-0376.pdf](#)

Assignor

Name: DEY PHARMA, L.P. **Execution Date:** Nov. 14, 2011

Legal Entity Type: LIMITED PARTNERSHIP **State or Country Where Organized:** DELAWARE

Name: MYLAN INSTITUTIONAL INC., (F/K/A UDL **Execution Date:** Nov. 14, 2011

LABORATORIES, INC.)

Legal Entity Type: CORPORATION
State or Country Where Organized: ILLINOIS

Name: MYLAN
PHARMACEUTICALS, INC. **Execution Date:** Nov. 14, 2011

Legal Entity Type: CORPORATION
State or Country Where Organized: WEST VIRGINIA

Name: MYLAN BERTEK
PHARMACEUTICALS INC.
(F/K/A BERTEK
PHARMACEUTICALS, INC.) **Execution Date:** Nov. 14, 2011

Legal Entity Type: CORPORATION
State or Country Where Organized: TEXAS

Name: MYLAN INC. (F/K/A MYLAN
LABORATORIES INC.) **Execution Date:** Nov. 14, 2011

Legal Entity Type: CORPORATION
State or Country Where Organized: PENNSYLVANIA

Name: SOMERSET
PHARMACEUTICALS, INC. **Execution Date:** Nov. 14, 2011

Legal Entity Type: CORPORATION
State or Country Where Organized: DELAWARE

Name: MYLAN TECHNOLOGIES,
INC. **Execution Date:** Nov. 14, 2011

Legal Entity Type: CORPORATION
State or Country Where Organized: WEST VIRGINIA

Assignee

Name: BANK OF AMERICA, N.A., AS ADMINISTRATIVE AGENT

State or Country

Legal Entity Type: ASSOCIATION

Where Organized: UNITED STATES

Address: 101 N TRYON STREET, NC1-001-05-45
ONE INDEPENDENCE CENTER
CHARLOTTE, NORTH CAROLINA USA 28255-0001

Correspondent

Correspondent Name: MICHAEL VIOLET

Correspondent Address: CT LIEN SOLUTIONS
4400 EASTON COMMONS WAY, SUITE 125
COLUMBUS, OH 43219

Domestic Representative - Not Found

EXHIBIT 3

Generated on: This page was generated by TSDR on 2012-09-04 10:04:04 EST

Mark: EIPEN JR. 2-PAK

EIPEN JR. 2-PAK

US Serial Number:	76286512	Application Filing Date:	Jul. 17, 2001
US Registration Number:	2576013	Registration Date:	Jun. 04, 2002
Register:	Principal		
Mark Type:	Trademark		
Status:	The registration has been renewed.		
Status Date:	Sep. 13, 2011		
Publication Date:	Mar. 12, 2002		

Mark Information

Mark Literal Elements:	EIPEN JR. 2-PAK
Standard Character Claim:	No
Mark Drawing Type:	1 - TYPESET WORD(S) /LETTER(S) /NUMBER(S)
Disclaimer:	"JR. 2 PACK"

Related Properties Information

Claimed Ownership of US Registrations: 1124454,1479294

Goods and Services

Note:

The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [...] indicate deleted goods/services;
- Double parenthesis ((.)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and

- Asterisks *..* identify additional (new) wording in the goods/services.

For: INJECTABLE PHARMACEUTICALS FOR TREATMENT OF ANAPHYLACTIC REACTIONS TO INSECT STINGS

International Class: 005 - Primary Class **U.S Class:** 006, 018, 044, 046, 051, 052

Class Status: ACTIVE

Basis: 1(a)

First Use: Apr. 02, 2001 **Use in Commerce:** Apr. 02, 2001

For: HYPODERMIC INJECTORS

International Class: 010 - Primary Class **U.S Class:** 026, 039, 044

Class Status: ACTIVE

Basis: 1(a)

First Use: Apr. 02, 2001 **Use in Commerce:** Apr. 02, 2001

Basis Information (Case Level)

Filed Use:	Yes	Currently Use:	Yes	Amended Use:	No
Filed ITU:	No	Currently ITU:	No	Amended ITU:	No
Filed 44D:	No	Currently 44D:	No	Amended 44D:	No
Filed 44E:	No	Currently 44E:	No	Amended 44E:	No
Filed 66A:	No	Currently 66A:	No		
Filed No Basis:	No	Currently No Basis:	No		

Current Owner(s) Information

Owner Name: MYLAN INC.

Owner Address: 1500 CORPORATE DRIVE
SUITE 400
CANONSBURG, PENNSYLVANIA 15317
UNITED STATES

Legal Entity Type: CORPORATION **State or Country Where Organized:** PENNSYLVANIA

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Michael A. Doctrow **Docket Number:** 24406-0007

Correspondent

Correspondent Name/Address: Michael A. Doctrow
McNees Wallace & Nurick
100 Pine Street
Harrisburg, PENNSYLVANIA 17108
UNITED STATES

Phone: 717-232-8000 **Fax:** 717-237-5300

Correspondent e-mail: trademarks@mwn.com **Correspondent e-mail Authorized:** Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
Feb. 01, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 04, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 04, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Dec. 07, 2011	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Sep. 13, 2011	REGISTERED AND RENEWED (FIRST RENEWAL - 10 YRS)	59136
Sep. 13, 2011	REGISTERED - SEC. 8 (10-YR) ACCEPTED/SEC. 9 GRANTED	59136
Jul. 15, 2011	TEAS SECTION 8 & 9 RECEIVED	
Nov. 18, 2008	REGISTERED - SEC. 8 (6-YR) ACCEPTED & SEC. 15 ACK.	59136
Nov. 04, 2008	TEAS SECTION 8 & 15 RECEIVED	
May 07, 2008	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	

Sep. 06, 2007	CASE FILE IN TICRS	
Jun. 04, 2002	REGISTERED-PRINCIPAL REGISTER	
Mar. 12, 2002	PUBLISHED FOR OPPOSITION	
Feb. 20, 2002	NOTICE OF PUBLICATION	
Nov. 30, 2001	APPROVED FOR PUB - PRINCIPAL REGISTER	
Oct. 29, 2001	EXAMINERS AMENDMENT MAILED	
Sep. 05, 2001	NON-FINAL ACTION MAILED	
Aug. 31, 2001	ASSIGNED TO EXAMINER	76629

Maintenance Filings or Post Registration Information

Affidavit of Continued Use: Section 8 - Accepted

Affidavit of Incontestability: Section 15 - Accepted

Renewal Date: Jun. 04, 2012

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location: Not Found **Date in Location:** Sep. 13, 2011

Assignment Abstract of Title Information

Summary

Total Assignments: 4 **Registrant:** EM Industries, Incorporated

Assignment 1 of 4

Conveyance: CHANGE OF NAME

Reel/Frame: 2560/0677 **Pages:** 3

Date Recorded: Aug. 19, 2002

Supporting Documents: assignment-tm-2560-0677.pdf

Assignor

Name: EM INDUSTRIES,
INCORPORATED

Execution Date: Jun. 27, 2002

Legal Entity Type: CORPORATION

**State or Country
Where
Organized:** No Place Where Organized
Found

Assignee

Name: EMD CHEMICALS INC.

Legal Entity Type: CORPORATION

**State or Country
Where
Organized:** NEW YORK

Address: 480 S. DEMOCRAT ROAD
GIBBSTOWN, NEW JERSEY 08027

Correspondent

**Correspondent
Name:** EMD CHEMICALS INC.

**Correspondent
Address:** SUSANNE F. DEAL, ESQ.
480 S. DEMOCRAT ROAD
GIBBSTOWN, NJ 06027

Domestic Representative - Not Found

Assignment 2 of 4

Conveyance: ASSIGNS THE ENTIRE INTEREST

Reel/Frame: 3772/0028

Pages: 10

Date Recorded: May 06, 2008

**Supporting
Documents:** assignment-tm-3772-0028.pdf

Assignor

Name: EMD CHEMICALS, INC.

Execution Date: Oct. 02, 2007

Legal Entity Type: CORPORATION

**State or Country
Where
Organized:** NEW YORK

Assignee

Name: MYLAN LABORATORIES, INC.

Legal Entity Type: CORPORATION

**State or Country
Where
Organized:** PENNSYLVANIA

Address: 1500 CORPORATE DRIVE
SUITE 400
CANONSBURG, PENNSYLVANIA 15317

Correspondent

Correspondent Name: SUE HEBERLIG
Correspondent Address: 100 PINE STREET
HARRISBURG, PA 17108

Domestic Representative - Not Found

Assignment 3 of 4

Conveyance: CHANGE OF NAME
Reel/Frame: 3772/0082 **Pages:** 7
Date Recorded: May 06, 2008
Supporting Documents: assignment-tm-3772-0082.pdf

Assignor

Name: MYLAN LABORATORIES, INC. **Execution Date:** Oct. 02, 2007
Legal Entity Type: CORPORATION **State or Country Where Organized:** PENNSYLVANIA

Assignee

Name: MYLAN INC. **State or Country Where Organized:** PENNSYLVANIA
Legal Entity Type: CORPORATION
Address: 1500 CORPORATE DRIVE
SUITE 400
CANONSBURG, PENNSYLVANIA 15317

Correspondent

Correspondent Name: SUE HEBERLIG
Correspondent Address: 100 PINE STREET
HARRISBURG, PA 17108

Domestic Representative - Not Found

Assignment 4 of 4

Conveyance: SECURITY AGREEMENT
Reel/Frame: 4704/0376 **Pages:** 26
Date Recorded: Nov. 21, 2011

Supporting Documents: [assignment-tm-4704-0376.pdf](#)

Assignor

Name: DEY PHARMA, L.P. **Execution Date:** Nov. 14, 2011
Legal Entity Type: LIMITED PARTNERSHIP **State or Country Where Organized:** DELAWARE

Name: MYLAN INSTITUTIONAL INC., (F/K/A UDL LABORATORIES, INC.) **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** ILLINOIS

Name: MYLAN PHARMACEUTICALS, INC. **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** WEST VIRGINIA

Name: MYLAN BERTEK PHARMACEUTICALS INC. (F/K/A BERTEK PHARMACEUTICALS, INC.) **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** TEXAS

Name: MYLAN INC. (F/K/A MYLAN LABORATORIES INC.) **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** PENNSYLVANIA

Name: SOMERSET PHARMACEUTICALS, INC. **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** DELAWARE

Name: MYLAN TECHNOLOGIES,
INC.

Execution Date: Nov. 14, 2011

Legal Entity Type: CORPORATION

**State or Country
Where
Organized:** WEST VIRGINIA

Assignee

Name: BANK OF AMERICA, N.A., AS ADMINISTRATIVE AGENT

Legal Entity Type: ASSOCIATION

**State or Country
Where
Organized:** UNITED STATES

Address: 101 N TRYON STREET, NC1-001-05-45
ONE INDEPENDENCE CENTER
CHARLOTTE, NORTH CAROLINA USA 28255-0001

Correspondent

**Correspondent
Name:** MICHAEL VIOLET

**Correspondent
Address:** CT LIEN SOLUTIONS
4400 EASTON COMMONS WAY, SUITE 125
COLUMBUS, OH 43219

Domestic Representative - Not Found

EXHIBIT 4

Generated on: This page was generated by TSDR on 2012-09-04 10:06:50 EST

Mark: EIPEN 2-PAK

EIPEN 2-PAK

US Serial Number:	76286513	Application Filing Date:	Jul. 17, 2001
US Registration Number:	2576014	Registration Date:	Jun. 04, 2002
Register:	Principal		
Mark Type:	Trademark		
Status:	The registration has been renewed.		
Status Date:	Sep. 06, 2011		
Publication Date:	Mar. 12, 2002		

Mark Information

Mark Literal Elements:	EIPEN 2-PAK
Standard Character Claim:	No
Mark Drawing Type:	1 - TYPESET WORD(S) /LETTER(S) /NUMBER(S)
Disclaimer:	"2 PACK"

Related Properties Information

Claimed Ownership of US Registrations: 1124454,1479294

Goods and Services

Note:

The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [...] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit

of incontestability; and

- Asterisks *.* identify additional (new) wording in the goods/services.

For: INJECTABLE PHARMACEUTICALS FOR TREATMENT OF ANAPHYLACTIC REACTIONS TO INSECT STINGS

International Class: 005 - Primary Class **U.S Class:** 006, 018, 044, 046, 051, 052

Class Status: ACTIVE

Basis: 1(a)

First Use: Apr. 02, 2001 **Use in Commerce:** Apr. 02, 2001

For: HYPODERMIC INJECTORS

International Class: 010 - Primary Class **U.S Class:** 026, 039, 044

Class Status: ACTIVE

Basis: 1(a)

First Use: Apr. 02, 2001 **Use in Commerce:** Apr. 02, 2001

Basis Information (Case Level)

Filed Use:	Yes	Currently Use:	Yes	Amended Use:	No
Filed ITU:	No	Currently ITU:	No	Amended ITU:	No
Filed 44D:	No	Currently 44D:	No	Amended 44D:	No
Filed 44E:	No	Currently 44E:	No	Amended 44E:	No
Filed 66A:	No	Currently 66A:	No		
Filed No Basis:	No	Currently No Basis:	No		

Current Owner(s) Information

Owner Name: MYLAN INC.

Owner Address: Suite 400
1500 Corporate Drive
Canonsburg, PENNSYLVANIA 15317
UNITED STATES

Legal Entity CORPORATION **State or Country Where** PENNSYLVANIA

Type:

Organized:

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Michael A. Doctrow

Docket Number: 24406-0007

Correspondent

**Correspondent
Name/Address:**

Michael A. Doctrow
McNees Wallace & Nurick
100 Pine Street
Harrisburg, PENNSYLVANIA 17108
UNITED STATES

Phone: 717-232-8000

Fax: 717-237-5300

**Correspondent e-
mail:**

trademarks@mwn.com

**Correspondent e-
mail Authorized:**

Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
Feb. 01, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 04, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 04, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Dec. 07, 2011	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Sep. 06, 2011	REGISTERED AND RENEWED (FIRST RENEWAL - 10 YRS)	59136
Sep. 06, 2011	REGISTERED - SEC. 8 (10-YR) ACCEPTED/SEC. 9 GRANTED	59136
Jul. 15, 2011	TEAS SECTION 8 & 9 RECEIVED	
Nov. 25, 2008	REGISTERED - SEC. 8 (6-YR) ACCEPTED & SEC. 15 ACK.	59136
Nov. 04, 2008	TEAS SECTION 8 & 15 RECEIVED	

May 07, 2008	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Sep. 06, 2007	CASE FILE IN TICRS	
Jun. 04, 2002	REGISTERED-PRINCIPAL REGISTER	
Mar. 12, 2002	PUBLISHED FOR OPPOSITION	
Feb. 20, 2002	NOTICE OF PUBLICATION	
Nov. 30, 2001	APPROVED FOR PUB - PRINCIPAL REGISTER	
Oct. 29, 2001	EXAMINERS AMENDMENT MAILED	
Sep. 05, 2001	NON-FINAL ACTION MAILED	
Aug. 31, 2001	ASSIGNED TO EXAMINER	76629

Maintenance Filings or Post Registration Information

Affidavit of Continued Use: Section 8 - Accepted

Affidavit of Incontestability: Section 15 - Accepted

Renewal Date: Jun. 04, 2012

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location: Not Found **Date in Location:** Sep. 06, 2011

Assignment Abstract of Title Information

Summary

Total Assignments: 4 **Registrant:** EM Industries, Incorporated

Assignment 1 of 4

Conveyance: CHANGE OF NAME

Reel/Frame: 2560/0677 **Pages:** 3

Date Recorded: Aug. 19, 2002

Supporting Documents: assignment-tm-2560-0677.pdf

Assignor

Name: EM INDUSTRIES, INCORPORATED **Execution Date:** Jun. 27, 2002
Legal Entity Type: CORPORATION **State or Country Where Organized:** No Place Where Organized Found

Assignee

Name: EMD CHEMICALS INC.
Legal Entity Type: CORPORATION **State or Country Where Organized:** NEW YORK
Address: 480 S. DEMOCRAT ROAD
GIBBSTOWN, NEW JERSEY 08027

Correspondent

Correspondent Name: EMD CHEMICALS INC.
Correspondent Address: SUSANNE F. DEAL, ESQ.
480 S. DEMOCRAT ROAD
GIBBSTOWN, NJ 06027

Domestic Representative - Not Found

Assignment 2 of 4

Conveyance: ASSIGNS THE ENTIRE INTEREST
Reel/Frame: 3772/0028 **Pages:** 10
Date Recorded: May 06, 2008
Supporting Documents: assignment-tm-3772-0028.pdf

Assignor

Name: EMD CHEMICALS, INC. **Execution Date:** Oct. 02, 2007
Legal Entity Type: CORPORATION **State or Country Where Organized:** NEW YORK

Assignee

Name: MYLAN LABORATORIES, INC.
Legal Entity Type: CORPORATION **State or Country Where Organized:** PENNSYLVANIA
1500 CORPORATE DRIVE

Address: SUITE 400
CANONSBURG, PENNSYLVANIA 15317

Correspondent

Correspondent Name: SUE HEBERLIG

Correspondent Address: 100 PINE STREET
HARRISBURG, PA 17108

Domestic Representative - Not Found

Assignment 3 of 4

Conveyance: CHANGE OF NAME

Reel/Frame: 3772/0082 **Pages:** 7

Date Recorded: May 06, 2008

Supporting Documents: assignment-tm-3772-0082.pdf

Assignor

Name: MYLAN LABORATORIES, INC. **Execution Date:** Oct. 02, 2007

Legal Entity Type: CORPORATION **State or Country Where Organized:** PENNSYLVANIA

Assignee

Name: MYLAN INC.

Legal Entity Type: CORPORATION **State or Country Where Organized:** PENNSYLVANIA

Address: 1500 CORPORATE DRIVE
SUITE 400
CANONSBURG, PENNSYLVANIA 15317

Correspondent

Correspondent Name: SUE HEBERLIG

Correspondent Address: 100 PINE STREET
HARRISBURG, PA 17108

Domestic Representative - Not Found

Assignment 4 of 4

Conveyance: SECURITY AGREEMENT

Reel/Frame: 4704/0376 **Pages:** 26

Date Recorded: Nov. 21, 2011

Supporting Documents: [assignment-tm-4704-0376.pdf](#)

Assignor

Name: DEY PHARMA, L.P. **Execution Date:** Nov. 14, 2011
Legal Entity Type: LIMITED PARTNERSHIP **State or Country Where Organized:** DELAWARE

Name: MYLAN INSTITUTIONAL INC., (F/K/A UDL LABORATORIES, INC.) **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** ILLINOIS

Name: MYLAN PHARMACEUTICALS, INC. **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** WEST VIRGINIA

Name: MYLAN BERTEK PHARMACEUTICALS INC. (F/K/A BERTEK PHARMACEUTICALS, INC.) **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** TEXAS

Name: MYLAN INC. (F/K/A MYLAN LABORATORIES INC.) **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** PENNSYLVANIA

Name: SOMERSET PHARMACEUTICALS, INC. **Execution Date:** Nov. 14, 2011

Legal Entity Type: CORPORATION

**State or Country
Where
Organized:** DELAWARE

Name: MYLAN TECHNOLOGIES,
INC.

Execution Date: Nov. 14, 2011

Legal Entity Type: CORPORATION

**State or Country
Where
Organized:** WEST VIRGINIA

Assignee

Name: BANK OF AMERICA, N.A., AS ADMINISTRATIVE AGENT

Legal Entity Type: ASSOCIATION

**State or Country
Where
Organized:** UNITED STATES

Address: 101 N TRYON STREET, NC1-001-05-45
ONE INDEPENDENCE CENTER
CHARLOTTE, NORTH CAROLINA USA 28255-0001

Correspondent

**Correspondent
Name:** MICHAEL VIOLET

**Correspondent
Address:** CT LIEN SOLUTIONS
4400 EASTON COMMONS WAY, SUITE 125
COLUMBUS, OH 43219

Domestic Representative - Not Found

EXHIBIT 5

Generated on: This page was generated by TSDR on 2012-09-04 10:09:09 EST

Mark: EIPEN-READY

EIPEN-READY

US Serial Number:	77919265	Application Filing Date:	Jan. 25, 2010
Filed as TEAS Plus:	Yes	Currently TEAS Plus:	Yes
Register:	Principal		
Mark Type:	Trademark		
Status:	A second request for extension of time to file a Statement of Use has been granted.		
Status Date:	May 01, 2012		
Publication Date:	Feb. 08, 2011	Notice of Allowance Date:	Apr. 05, 2011

Mark Information

Mark Literal Elements:	EIPEN-READY
Standard Character Claim:	Yes. The mark consists of standard characters without claim to any particular font style, size, or color.
Mark Drawing Type:	4 - STANDARD CHARACTER MARK

Related Properties Information

Claimed Ownership of US Registrations: 1124454,1479294,2576013,and others

Goods and Services

Note:

The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [...] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and

- Asterisks *..* identify additional (new) wording in the goods/services.

For: Injectable pharmaceuticals for treatment of anaphylactic reactions

International Class: 005 - Primary Class

U.S Class: 006, 018, 044, 046, 051, 052

Class Status: ACTIVE

Basis: 1(b)

For: Medical fluid injectors

International Class: 010 - Primary Class

U.S Class: 026, 039, 044

Class Status: ACTIVE

Basis: 1(b)

Basis Information (Case Level)

Filed Use:	No	Currently Use:	No	Amended Use:	No
Filed ITU:	Yes	Currently ITU:	Yes	Amended ITU:	No
Filed 44D:	No	Currently 44D:	No	Amended 44D:	No
Filed 44E:	No	Currently 44E:	No	Amended 44E:	No
Filed 66A:	No	Currently 66A:	No		
Filed No Basis:	No	Currently No Basis:	No		

Current Owner(s) Information

Owner Name: Mylan Inc.

Suite 400
1500 Corporate Drive
Canonsburg, PENNSYLVANIA 15317
UNITED STATES

Owner Address:

Legal Entity Type: CORPORATION

State or Country Where Organized: PENNSYLVANIA

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Michael A. Doctrow

Docket Number: 24406-0007

Correspondent

**Correspondent
Name/Address:**

MICHAEL A. DOCTROW
MCNEES WALLACE & NURICK
100 PINE ST
HARRISBURG, PENNSYLVANIA 17101-1200
UNITED STATES

Phone: 717-232-8000

Fax: 717-237-5300

**Correspondent e-
mail:** trademarks@mwn.com

**Correspondent e-
mail Authorized:** Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
May 02, 2012	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
May 01, 2012	EXTENSION 2 GRANTED	66530
Apr. 03, 2012	EXTENSION 2 FILED	66530
Apr. 27, 2012	CASE ASSIGNED TO INTENT TO USE PARALEGAL	66530
Apr. 03, 2012	TEAS EXTENSION RECEIVED	
Feb. 01, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 04, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 04, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Dec. 07, 2011	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Oct. 06, 2011	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Oct. 04, 2011	EXTENSION 1 GRANTED	98765
Oct. 04, 2011	EXTENSION 1 FILED	98765
Oct. 04, 2011	TEAS EXTENSION RECEIVED	
Apr. 05, 2011	NOA E-MAILED - SOU REQUIRED FROM APPLICANT	

Feb. 08, 2011	OFFICIAL GAZETTE PUBLICATION CONFIRMATION E-MAILED	
Feb. 08, 2011	PUBLISHED FOR OPPOSITION	
Jan. 03, 2011	LAW OFFICE PUBLICATION REVIEW COMPLETED	67287
Dec. 26, 2010	APPROVED FOR PUB - PRINCIPAL REGISTER	
Nov. 16, 2010	AMENDMENT FROM APPLICANT ENTERED	67287
Nov. 16, 2010	CORRESPONDENCE RECEIVED IN LAW OFFICE	67287
Nov. 16, 2010	ASSIGNED TO LIE	67287
Oct. 27, 2010	PAPER RECEIVED	
Apr. 25, 2010	NOTIFICATION OF NON-FINAL ACTION E-MAILED	6325
Apr. 25, 2010	NON-FINAL ACTION E-MAILED	6325
Apr. 25, 2010	NON-FINAL ACTION WRITTEN	59851
Apr. 22, 2010	ASSIGNED TO EXAMINER	59851
Jan. 29, 2010	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
Jan. 28, 2010	NEW APPLICATION ENTERED IN TRAM	

TM Staff and Location Information

TM Staff Information

TM Attorney: FISHER, HANNAH M **Law Office Assigned:** LAW OFFICE 111

File Location

Current Location: INTENT TO USE SECTION **Date in Location:** Apr. 27, 2012

Assignment Abstract of Title Information

Summary

Total Assignments: 1 **Applicant:** Mylan Inc.

Assignment 1 of 1

Conveyance: SECURITY AGREEMENT

Reel/Frame: 4704/0376 **Pages:** 26

Date Recorded: Nov. 21, 2011

Supporting Documents: [assignment-tm-4704-0376.pdf](#)

Assignor

Name: DEY PHARMA, L.P. **Execution Date:** Nov. 14, 2011
Legal Entity Type: LIMITED PARTNERSHIP **State or Country Where Organized:** DELAWARE

Name: MYLAN INSTITUTIONAL INC., (F/K/A UDL LABORATORIES, INC.) **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** ILLINOIS

Name: MYLAN PHARMACEUTICALS, INC. **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** WEST VIRGINIA

Name: MYLAN BERTEK PHARMACEUTICALS INC. (F/K/A BERTEK PHARMACEUTICALS, INC.) **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** TEXAS

Name: MYLAN INC. (F/K/A MYLAN LABORATORIES INC.) **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** PENNSYLVANIA

Name: SOMERSET PHARMACEUTICALS, INC. **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** DELAWARE

Name: MYLAN TECHNOLOGIES, INC. **Execution Date:** Nov. 14, 2011

Legal Entity Type: CORPORATION **State or Country Where Organized:** WEST VIRGINIA

Assignee

Name: BANK OF AMERICA, N.A., AS ADMINISTRATIVE AGENT

Legal Entity Type: ASSOCIATION **State or Country Where Organized:** UNITED STATES

Address: 101 N TRYON STREET, NC1-001-05-45
ONE INDEPENDENCE CENTER
CHARLOTTE, NORTH CAROLINA USA 28255-0001

Correspondent

Correspondent Name: MICHAEL VIOLET

Correspondent Address: CT LIEN SOLUTIONS
4400 EASTON COMMONS WAY, SUITE 125
COLUMBUS, OH 43219

Domestic Representative - Not Found

EXHIBIT 6

Generated on: This page was generated by TSDR on 2012-09-04 10:10:48 EST

Mark: EIPEN PREPARED

EIPEN PREPARED

US Serial Number:	77919257	Application Filing Date:	Jan. 25, 2010
Filed as TEAS Plus:	Yes	Currently TEAS Plus:	Yes
Register:	Principal		
Mark Type:	Trademark		
Status:	A fourth request for extension of time to file a Statement of Use has been granted.		
Status Date:	Aug. 09, 2012		
Publication Date:	Jun. 08, 2010	Notice of Allowance Date:	Aug. 03, 2010

Mark Information

Mark Literal Elements:	EIPEN PREPARED
Standard Character Claim:	Yes. The mark consists of standard characters without claim to any particular font style, size, or color.
Mark Drawing Type:	4 - STANDARD CHARACTER MARK

Related Properties Information

Claimed Ownership of US Registrations: 1124454,1479294,2576013, and others

Goods and Services

Note:

The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [...] indicate deleted goods/services;
- Double parenthesis ((.)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and

- Asterisks *..* identify additional (new) wording in the goods/services.

For: Injectable pharmaceuticals for treatment of anaphylactic reactions
International Class: 005 - Primary Class **U.S Class:** 006, 018, 044, 046, 051, 052
Class Status: ACTIVE
Basis: 1(b)

For: Medical fluid injectors
International Class: 010 - Primary Class **U.S Class:** 026, 039, 044
Class Status: ACTIVE
Basis: 1(b)

Basis Information (Case Level)

Filed Use:	No	Currently Use:	No	Amended Use:	No
Filed ITU:	Yes	Currently ITU:	Yes	Amended ITU:	No
Filed 44D:	No	Currently 44D:	No	Amended 44D:	No
Filed 44E:	No	Currently 44E:	No	Amended 44E:	No
Filed 66A:	No	Currently 66A:	No		
Filed No Basis:	No	Currently No Basis:	No		

Current Owner(s) Information

Owner Name: Mylan Inc.
1500 Corporate Drive, Suite 400
Owner Address: Canonsburg, PENNSYLVANIA 15317
UNITED STATES

Legal Entity Type:	CORPORATION	State or Country Where Organized:	PENNSYLVANIA
---------------------------	-------------	--	--------------

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Michael A. Doctrow **Docket Number:** 24406-0007

Correspondent

Correspondent Name/Address: MICHAEL A. DOCTROW
MCNEES WALLACE & NURICK
100 PINE ST
HARRISBURG, PENNSYLVANIA 17101-1200
UNITED STATES

Phone: 717-232-8000

Fax: 717-237-5300

Correspondent e-mail: trademarks@mwn.com

Correspondent e-mail Authorized: Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
Aug. 10, 2012	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Aug. 09, 2012	EXTENSION 4 GRANTED	70565
Aug. 03, 2012	EXTENSION 4 FILED	70565
Aug. 03, 2012	TEAS EXTENSION RECEIVED	
Feb. 01, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 24, 2012	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Jan. 21, 2012	EXTENSION 3 GRANTED	70565
Jan. 19, 2012	EXTENSION 3 FILED	70565
Jan. 19, 2012	TEAS EXTENSION RECEIVED	
Jan. 04, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 04, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Dec. 07, 2011	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Aug. 09, 2011	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Aug. 08, 2011	EXTENSION 2 GRANTED	70565

Aug. 02, 2011	EXTENSION 2 FILED	70565
Aug. 02, 2011	TEAS EXTENSION RECEIVED	
Feb. 17, 2011	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Feb. 16, 2011	EXTENSION 1 GRANTED	70565
Jan. 28, 2011	EXTENSION 1 FILED	70565
Feb. 16, 2011	CASE ASSIGNED TO INTENT TO USE PARALEGAL	70565
Jan. 28, 2011	TEAS EXTENSION RECEIVED	
Aug. 03, 2010	NOA E-MAILED - SOU REQUIRED FROM APPLICANT	
Jun. 08, 2010	OFFICIAL GAZETTE PUBLICATION CONFIRMATION E-MAILED	
Jun. 08, 2010	PUBLISHED FOR OPPOSITION	
May 05, 2010	LAW OFFICE PUBLICATION REVIEW COMPLETED	66213
May 05, 2010	ASSIGNED TO LIE	66213
Apr. 24, 2010	APPROVED FOR PUB - PRINCIPAL REGISTER	
Apr. 22, 2010	ASSIGNED TO EXAMINER	59851
Jan. 29, 2010	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
Jan. 28, 2010	NEW APPLICATION ENTERED IN TRAM	

TM Staff and Location Information

TM Staff Information

TM Attorney:	FISHER, HANNAH M	Law Office Assigned:	LAW OFFICE 111
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File Location

Current Location: INTENT TO USE SECTION **Date in Location:** Feb. 16, 2011

Assignment Abstract of Title Information

Summary

Total Assignments:	1	Applicant:	Mylan Inc.
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Assignment 1 of 1

Conveyance: SECURITY AGREEMENT

Reel/Frame: 4704/0376

Pages: 26

Date Recorded: Nov. 21, 2011

Supporting Documents: assignment-tm-4704-0376.pdf

Assignor

Name: DEY PHARMA, L.P.

Execution Date: Nov. 14, 2011

Legal Entity Type: LIMITED PARTNERSHIP

State or Country Where Organized: DELAWARE

Name: MYLAN INSTITUTIONAL INC., (F/K/A UDL LABORATORIES, INC.)

Execution Date: Nov. 14, 2011

Legal Entity Type: CORPORATION

State or Country Where Organized: ILLINOIS

Name: MYLAN PHARMACEUTICALS, INC.

Execution Date: Nov. 14, 2011

Legal Entity Type: CORPORATION

State or Country Where Organized: WEST VIRGINIA

Name: MYLAN BERTEK PHARMACEUTICALS INC. (F/K/A BERTEK PHARMACEUTICALS, INC.)

Execution Date: Nov. 14, 2011

Legal Entity Type: CORPORATION

State or Country Where Organized: TEXAS

Name: MYLAN INC. (F/K/A MYLAN LABORATORIES INC.)

Execution Date: Nov. 14, 2011

Legal Entity Type: CORPORATION

State or Country Where Organized: PENNSYLVANIA

Name: SOMERSET

Execution Date: Nov. 14, 2011

PHARMACEUTICALS, INC.

Legal Entity Type: CORPORATION **State or Country Where Organized:** DELAWARE

Name: MYLAN TECHNOLOGIES, INC. **Execution Date:** Nov. 14, 2011

Legal Entity Type: CORPORATION **State or Country Where Organized:** WEST VIRGINIA

Assignee

Name: BANK OF AMERICA, N.A., AS ADMINISTRATIVE AGENT

Legal Entity Type: ASSOCIATION **State or Country Where Organized:** UNITED STATES

Address: 101 N TRYON STREET, NC1-001-05-45
ONE INDEPENDENCE CENTER
CHARLOTTE, NORTH CAROLINA USA 28255-0001

Correspondent

Correspondent Name: MICHAEL VIOLET

Correspondent Address: CT LIEN SOLUTIONS
4400 EASTON COMMONS WAY, SUITE 125
COLUMBUS, OH 43219

Domestic Representative - Not Found

EXHIBIT 7

Generated on: This page was generated by TSDR on 2012-09-04 10:14:20 EST

Mark: EPI-PREPARED

EPI-PREPARED

US Serial Number:	77919269	Application Filing Date:	Jan. 25, 2010
Filed as TEAS Plus:	Yes	Currently TEAS Plus:	Yes
Register:	Principal		
Mark Type:	Trademark		
Status:	A fourth request for extension of time to file a Statement of Use has been granted.		
Status Date:	Aug. 09, 2012		
Publication Date:	Jun. 08, 2010	Notice of Allowance Date:	Aug. 03, 2010

Mark Information

Mark Literal Elements:	EPI-PREPARED
Standard Character Claim:	Yes. The mark consists of standard characters without claim to any particular font style, size, or color.
Mark Drawing Type:	4 - STANDARD CHARACTER MARK

Related Properties Information

Claimed Ownership of US Registrations: 1124454,1479294,2576013, and others

Goods and Services

Note:

The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [...] indicate deleted goods/services;
- Double parenthesis ((.)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and

- Asterisks *..* identify additional (new) wording in the goods/services.

For: Injectable pharmaceuticals for treatment of anaphylactic reactions
International Class: 005 - Primary Class **U.S Class:** 006, 018, 044, 046, 051, 052
Class Status: ACTIVE
Basis: 1(b)

For: Medical fluid injectors
International Class: 010 - Primary Class **U.S Class:** 026, 039, 044
Class Status: ACTIVE
Basis: 1(b)

Basis Information (Case Level)

Filed Use:	No	Currently Use:	No	Amended Use:	No
Filed ITU:	Yes	Currently ITU:	Yes	Amended ITU:	No
Filed 44D:	No	Currently 44D:	No	Amended 44D:	No
Filed 44E:	No	Currently 44E:	No	Amended 44E:	No
Filed 66A:	No	Currently 66A:	No		
Filed No Basis:	No	Currently No Basis:	No		

Current Owner(s) Information

Owner Name: Mylan Inc.
Suite 400
Owner Address: 1500 Corporate Drive
Canonsburg, PENNSYLVANIA 15317
UNITED STATES

Legal Entity Type: CORPORATION **State or Country Where Organized:** PENNSYLVANIA

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Michael A. Doctrow

Docket Number: 24406-0007

Correspondent

Correspondent Name/Address: MICHAEL A. DOCTROW
MCNEES WALLACE & NURICK
100 PINE ST
HARRISBURG, PENNSYLVANIA 17101-1200
UNITED STATES

Phone: 717-232-8000

Fax: 717-237-5300

Correspondent e-mail: trademarks@mwn.com

Correspondent e-mail Authorized: Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
Aug. 10, 2012	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Aug. 09, 2012	EXTENSION 4 GRANTED	70565
Aug. 03, 2012	EXTENSION 4 FILED	70565
Aug. 03, 2012	TEAS EXTENSION RECEIVED	
Feb. 01, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 25, 2012	NOTICE OF APPROVAL OF EXTENSION REQUEST MAILED	
Jan. 21, 2012	EXTENSION 3 GRANTED	70565
Jan. 19, 2012	EXTENSION 3 FILED	70565
Jan. 19, 2012	TEAS EXTENSION RECEIVED	
Jan. 04, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 04, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Aug. 09, 2011	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Aug. 08, 2011	EXTENSION 2 GRANTED	70565
Aug. 02, 2011	EXTENSION 2 FILED	70565

Aug. 02, 2011	TEAS EXTENSION RECEIVED	
Feb. 17, 2011	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Feb. 16, 2011	EXTENSION 1 GRANTED	70565
Jan. 28, 2011	EXTENSION 1 FILED	70565
Feb. 16, 2011	CASE ASSIGNED TO INTENT TO USE PARALEGAL	70565
Jan. 28, 2011	TEAS EXTENSION RECEIVED	
Aug. 03, 2010	NOA E-MAILED - SOU REQUIRED FROM APPLICANT	
Jun. 08, 2010	OFFICIAL GAZETTE PUBLICATION CONFIRMATION E-MAILED	
Jun. 08, 2010	PUBLISHED FOR OPPOSITION	
May 05, 2010	LAW OFFICE PUBLICATION REVIEW COMPLETED	66213
May 05, 2010	ASSIGNED TO LIE	66213
Apr. 24, 2010	APPROVED FOR PUB - PRINCIPAL REGISTER	
Apr. 22, 2010	ASSIGNED TO EXAMINER	59851
Jan. 29, 2010	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
Jan. 28, 2010	NEW APPLICATION ENTERED IN TRAM	

TM Staff and Location Information

TM Staff Information

TM Attorney:	FISHER, HANNAH M	Law Office Assigned:	LAW OFFICE 111
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File Location

Current Location: INTENT TO USE SECTION **Date in Location:** Feb. 16, 2011

Assignment Abstract of Title Information

Summary

Total Assignments:	1	Applicant:	Mylan Inc.
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Assignment 1 of 1

Conveyance: SECURITY AGREEMENT

Reel/Frame: 4704/0376

Pages: 26

Date Recorded: Nov. 21, 2011

Supporting Documents: [assignment-tm-4704-0376.pdf](#)

Assignor

Name: DEY PHARMA, L.P. Execution Date: Nov. 14, 2011
Legal Entity Type: LIMITED PARTNERSHIP State or Country Where Organized: DELAWARE

Name: MYLAN INSTITUTIONAL INC., (F/K/A UDL LABORATORIES, INC.) Execution Date: Nov. 14, 2011
Legal Entity Type: CORPORATION State or Country Where Organized: ILLINOIS

Name: MYLAN PHARMACEUTICALS, INC. Execution Date: Nov. 14, 2011
Legal Entity Type: CORPORATION State or Country Where Organized: WEST VIRGINIA

Name: MYLAN BERTEK PHARMACEUTICALS INC. (F/K/A BERTEK PHARMACEUTICALS, INC.) Execution Date: Nov. 14, 2011
Legal Entity Type: CORPORATION State or Country Where Organized: TEXAS

Name: MYLAN INC. (F/K/A MYLAN LABORATORIES INC.) Execution Date: Nov. 14, 2011
Legal Entity Type: CORPORATION State or Country Where Organized: PENNSYLVANIA

Name: SOMERSET PHARMACEUTICALS, INC. Execution Date: Nov. 14, 2011

Legal Entity Type: CORPORATION

**State or
Country Where
Organized:** DELAWARE

Name: MYLAN TECHNOLOGIES,
INC.

Execution Date: Nov. 14, 2011

Legal Entity Type: CORPORATION

**State or
Country Where
Organized:** WEST VIRGINIA

Assignee

Name: BANK OF AMERICA, N.A., AS ADMINISTRATIVE AGENT

Legal Entity Type: ASSOCIATION

**State or
Country Where
Organized:** UNITED STATES

Address: 101 N TRYON STREET, NC1-001-05-45
ONE INDEPENDENCE CENTER
CHARLOTTE, NORTH CAROLINA USA 28255-0001

Correspondent

**Correspondent
Name:** MICHAEL VIOLET

**Correspondent
Address:** CT LIEN SOLUTIONS
4400 EASTON COMMONS WAY, SUITE 125
COLUMBUS, OH 43219

Domestic Representative - Not Found

EXHIBIT 8

Generated on: This page was generated by TSDR on 2012-09-04 10:16:52 EST

Mark: EPI-SET

EPI-SET

US Serial Number: 77919271

Application Filing Date: Jan. 25, 2010

Filed as TEAS Plus: Yes

Currently TEAS Plus: Yes

Register: Principal

Mark Type: Trademark

Status: A second request for extension of time to file a Statement of Use has been granted.

Status Date: May 01, 2012

Publication Date: Feb. 08, 2011

Notice of Allowance Date: Apr. 05, 2011

Mark Information

Mark Literal Elements: EPI-SET

Standard Character Claim: Yes. The mark consists of standard characters without claim to any particular font style, size, or color.

Mark Drawing Type: 4 - STANDARD CHARACTER MARK

Related Properties Information

Claimed Ownership of US Registrations: 1124454,1479294,2576013,and others

Goods and Services

Note:

The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [...] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and

- Asterisks *.* identify additional (new) wording in the goods/services.

For: Injectable pharmaceuticals for treatment of anaphylactic reactions

International Class: 005 - Primary Class

U.S Class: 006, 018, 044, 046, 051, 052

Class Status: ACTIVE

Basis: 1(b)

For: Medical fluid injectors

International Class: 010 - Primary Class

U.S Class: 026, 039, 044

Class Status: ACTIVE

Basis: 1(b)

Basis Information (Case Level)

Filed Use:	No	Currently Use:	No	Amended Use:	No
Filed ITU:	Yes	Currently ITU:	Yes	Amended ITU:	No
Filed 44D:	No	Currently 44D:	No	Amended 44D:	No
Filed 44E:	No	Currently 44E:	No	Amended 44E:	No
Filed 66A:	No	Currently 66A:	No		
Filed No Basis:	No	Currently No Basis:	No		

Current Owner(s) Information

Owner Name: Mylan Inc.

Suite 400
1500 Corporate Drive
Canonsburg, PENNSYLVANIA 15317
UNITED STATES

Owner Address:

Legal Entity Type: CORPORATION

State or Country Where Organized: PENNSYLVANIA

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Michael A. Doctrow

Docket Number: 24406-0007

Correspondent

**Correspondent
Name/Address:**

MICHAEL A. DOCTROW
MCNEES WALLACE & NURICK
100 PINE ST
HARRISBURG, PENNSYLVANIA 17101-1200
UNITED STATES

Phone: 717-232-8000

Fax: 717-237-5300

**Correspondent e-
mail:** trademarks@mwn.com

**Correspondent e-
mail Authorized:** Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
May 02, 2012	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
May 01, 2012	EXTENSION 2 GRANTED	66530
Apr. 03, 2012	EXTENSION 2 FILED	66530
Apr. 27, 2012	CASE ASSIGNED TO INTENT TO USE PARALEGAL	66530
Apr. 03, 2012	TEAS EXTENSION RECEIVED	
Feb. 01, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 04, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 04, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Dec. 07, 2011	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Oct. 06, 2011	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Oct. 04, 2011	EXTENSION 1 GRANTED	98765
Oct. 04, 2011	EXTENSION 1 FILED	98765
Oct. 04, 2011	TEAS EXTENSION RECEIVED	
Apr. 05, 2011	NOA E-MAILED - SOU REQUIRED FROM APPLICANT	

Feb. 08, 2011	OFFICIAL GAZETTE PUBLICATION CONFIRMATION E-MAILED	
Feb. 08, 2011	PUBLISHED FOR OPPOSITION	
Jan. 03, 2011	LAW OFFICE PUBLICATION REVIEW COMPLETED	67287
Dec. 26, 2010	APPROVED FOR PUB - PRINCIPAL REGISTER	
Nov. 16, 2010	AMENDMENT FROM APPLICANT ENTERED	67287
Nov. 16, 2010	CORRESPONDENCE RECEIVED IN LAW OFFICE	67287
Nov. 16, 2010	ASSIGNED TO LIE	67287
Oct. 27, 2010	PAPER RECEIVED	
Apr. 25, 2010	NOTIFICATION OF NON-FINAL ACTION E-MAILED	6325
Apr. 25, 2010	NON-FINAL ACTION E-MAILED	6325
Apr. 25, 2010	NON-FINAL ACTION WRITTEN	59851
Apr. 22, 2010	ASSIGNED TO EXAMINER	59851
Jan. 29, 2010	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
Jan. 28, 2010	NEW APPLICATION ENTERED IN TRAM	

TM Staff and Location Information

TM Staff Information

TM Attorney: FISHER, HANNAH M **Law Office Assigned:** LAW OFFICE 111

File Location

Current Location: INTENT TO USE SECTION **Date in Location:** Apr. 27, 2012

Assignment Abstract of Title Information

Summary

Total Assignments: 1 **Applicant:** Mylan Inc.

Assignment 1 of 1

Conveyance: SECURITY AGREEMENT

Reel/Frame: 4704/0376 **Pages:** 26

Date Recorded: Nov. 21, 2011

Supporting Documents: [assignment-tm-4704-0376.pdf](#)

Assignor

Name: DEY PHARMA, L.P. **Execution Date:** Nov. 14, 2011
Legal Entity Type: LIMITED PARTNERSHIP **State or Country Where Organized:** DELAWARE

Name: MYLAN INSTITUTIONAL INC., (F/K/A UDL LABORATORIES, INC.) **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** ILLINOIS

Name: MYLAN PHARMACEUTICALS, INC. **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** WEST VIRGINIA

Name: MYLAN BERTEK PHARMACEUTICALS INC. (F/K/A BERTEK PHARMACEUTICALS, INC.) **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** TEXAS

Name: MYLAN INC. (F/K/A MYLAN LABORATORIES INC.) **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** PENNSYLVANIA

Name: SOMERSET PHARMACEUTICALS, INC. **Execution Date:** Nov. 14, 2011
Legal Entity Type: CORPORATION **State or Country Where Organized:** DELAWARE

Name: MYLAN TECHNOLOGIES, INC. **Execution Date:** Nov. 14, 2011

Legal Entity Type: CORPORATION **State or Country Where Organized:** WEST VIRGINIA

Assignee

Name: BANK OF AMERICA, N.A., AS ADMINISTRATIVE AGENT

Legal Entity Type: ASSOCIATION **State or Country Where Organized:** UNITED STATES

Address: 101 N TRYON STREET, NC1-001-05-45
ONE INDEPENDENCE CENTER
CHARLOTTE, NORTH CAROLINA USA 28255-0001

Correspondent

Correspondent Name: MICHAEL VIOLET

Correspondent Address: CT LIEN SOLUTIONS
4400 EASTON COMMONS WAY, SUITE 125
COLUMBUS, OH 43219

Domestic Representative - Not Found

EXHIBIT 9

Generated on: This page was generated by TSDR on 2012-09-04 10:18:24 EST

Mark: EPICARD

EPICARD

US Serial Number: 77927738

Application Filing Date: Feb. 04, 2010

Register: Principal

Mark Type: Trademark

Status: A first request for extension of time to file a Statement of Use has been granted.

Status Date: Apr. 30, 2012

Publication Date: Sep. 06, 2011

Notice of Allowance Date: Nov. 01, 2011

Mark Information

Mark Literal Elements: EPICARD

Standard Character Claim: Yes. The mark consists of standard characters without claim to any particular font style, size, or color.

Mark Drawing Type: 4 - STANDARD CHARACTER MARK

Related Properties Information

Claimed Ownership of US Registrations: 1124454,1479294,2576013,and others

Goods and Services

Note:

The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [...] indicate deleted goods/services;
- Double parenthesis ((.)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks *..* identify additional (new) wording in the goods/services.

For: printed multilingual instructional material regarding the purpose and use of epinephrine auto injectors

International Class: 016 - Primary Class

U.S Class: 002, 005, 022, 023, 029, 037, 038, 050

Class Status: ACTIVE

Basis: 1(b)

Basis Information (Case Level)

Filed Use:	No	Currently Use:	No	Amended Use:	No
Filed ITU:	Yes	Currently ITU:	Yes	Amended ITU:	No
Filed 44D:	No	Currently 44D:	No	Amended 44D:	No
Filed 44E:	No	Currently 44E:	No	Amended 44E:	No
Filed 66A:	No	Currently 66A:	No		
Filed No Basis:	No	Currently No Basis:	No		

Current Owner(s) Information

Owner Name: Mylan Inc.

Owner Address: 1500 Corporate Drive
Canonsburg, PENNSYLVANIA 15317
UNITED STATES

Legal Entity Type: CORPORATION

State or Country Where Organized: PENNSYLVANIA

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Michael A. Doctrow

Docket Number: 24406-0001

Correspondent

Correspondent Name/Address:

MICHAEL A. DOCTROW
MCNEES WALLACE & NURICK
100 PINE ST
HARRISBURG, PENNSYLVANIA 17101-1200
UNITED STATES

Phone: 717-232-8000

Fax: 717-237-5300

Correspondent e-mail: trademarks@mwn.com

Correspondent e-mail Authorized: Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
May 02, 2012	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Apr. 30, 2012	EXTENSION 1 GRANTED	98765
Apr. 30, 2012	EXTENSION 1 FILED	98765
Apr. 30, 2012	TEAS EXTENSION RECEIVED	
Feb. 01, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 04, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Jan. 04, 2012	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Dec. 07, 2011	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Nov. 01, 2011	NOA E-MAILED - SOU REQUIRED FROM APPLICANT	
Sep. 06, 2011	OFFICIAL GAZETTE PUBLICATION CONFIRMATION E-MAILED	
Sep. 06, 2011	PUBLISHED FOR OPPOSITION	
Aug. 03, 2011	LAW OFFICE PUBLICATION REVIEW COMPLETED	66213
Jul. 28, 2011	APPROVED FOR PUB - PRINCIPAL REGISTER	
Jul. 01, 2011	AMENDMENT FROM APPLICANT ENTERED	66213
Jul. 01, 2011	CORRESPONDENCE RECEIVED IN LAW OFFICE	66213
Jun. 29, 2011	PAPER RECEIVED	
Dec. 26, 2010	NOTIFICATION OF FINAL REFUSAL EMAILED	
Dec. 26, 2010	FINAL REFUSAL E-MAILED	
Dec. 26, 2010	FINAL REFUSAL WRITTEN	59851
Nov. 16, 2010	AMENDMENT FROM APPLICANT ENTERED	66213

Nov. 16, 2010	CORRESPONDENCE RECEIVED IN LAW OFFICE	66213
Nov. 16, 2010	ASSIGNED TO LIE	66213
Oct. 27, 2010	PAPER RECEIVED	
Apr. 26, 2010	NOTIFICATION OF NON-FINAL ACTION E-MAILED	6325
Apr. 26, 2010	NON-FINAL ACTION E-MAILED	6325
Apr. 26, 2010	NON-FINAL ACTION WRITTEN	59851
Apr. 22, 2010	ASSIGNED TO EXAMINER	59851
Feb. 13, 2010	NOTICE OF PSEUDO MARK MAILED	
Feb. 12, 2010	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
Feb. 08, 2010	NEW APPLICATION ENTERED IN TRAM	

TM Staff and Location Information

TM Staff Information

TM Attorney: FISHER, HANNAH M **Law Office Assigned:** LAW OFFICE 111

File Location

Current Location: INTENT TO USE SECTION **Date in Location:** Nov. 01, 2011

Assignment Abstract of Title Information

Summary

Total Assignments: 1 **Applicant:** Mylan Inc.

Assignment 1 of 1

Conveyance: SECURITY AGREEMENT

Reel/Frame: 4704/0376 **Pages:** 26

Date Recorded: Nov. 21, 2011

Supporting Documents: assignment-tm-4704-0376.pdf

Assignor

Name: DEY PHARMA, L.P. **Execution Date:** Nov. 14, 2011

Legal Entity Type: LIMITED PARTNERSHIP **State or Country Where:** DELAWARE

Organized:

Name:	<u>MYLAN INSTITUTIONAL INC., (F/K/A UDL LABORATORIES, INC.)</u>	Execution Date:	Nov. 14, 2011
Legal Entity Type:	CORPORATION	State or Country Where Organized:	ILLINOIS

Name:	<u>MYLAN PHARMACEUTICALS, INC.</u>	Execution Date:	Nov. 14, 2011
Legal Entity Type:	CORPORATION	State or Country Where Organized:	WEST VIRGINIA

Name:	<u>MYLAN BERTEK PHARMACEUTICALS INC. (F/K/A BERTEK PHARMACEUTICALS, INC.)</u>	Execution Date:	Nov. 14, 2011
Legal Entity Type:	CORPORATION	State or Country Where Organized:	TEXAS

Name:	<u>MYLAN INC. (F/K/A MYLAN LABORATORIES INC.)</u>	Execution Date:	Nov. 14, 2011
Legal Entity Type:	CORPORATION	State or Country Where Organized:	PENNSYLVANIA

Name:	<u>SOMERSET PHARMACEUTICALS, INC.</u>	Execution Date:	Nov. 14, 2011
Legal Entity Type:	CORPORATION	State or Country Where Organized:	DELAWARE

Name:	<u>MYLAN TECHNOLOGIES, INC.</u>	Execution Date:	Nov. 14, 2011
Legal Entity Type:	CORPORATION	State or Country Where Organized:	WEST VIRGINIA

Assignee

Name: BANK OF AMERICA, N.A., AS ADMINISTRATIVE AGENT

Legal Entity Type: ASSOCIATION
State or Country Where Organized: UNITED STATES

Address: 101 N TRYON STREET, NC1-001-05-45
ONE INDEPENDENCE CENTER
CHARLOTTE, NORTH CAROLINA USA 28255-0001

Correspondent

Correspondent Name: MICHAEL VIOLET

Correspondent Address: CT LIEN SOLUTIONS
4400 EASTON COMMONS WAY, SUITE 125
COLUMBUS, OH 43219

Domestic Representative - Not Found

EXHIBIT 10

**THOMAS C. BELLER
DISCOVERY DEPOSITION
FEBRUARY 13, 2012
(EXCERPTS)**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

MYLAN, INC.,

Opposer,

vs.

OPPOSITION NUMBER
91195868

BEAUFORT COUNTY ALLERGY,

Applicant.

-----/

The deposition of THOMAS CHARLES BELLER,
M.D., a witness in the above-entitled cause,
taken pursuant to Notice and agreement, before
Kyle J. Saniga, Certified Court Reporter and
Notary Public, at the Offices of Raymond James,
27 Towne Drive, Suite 202, Hilton Head, South
Carolina 29910, on the 13th day of February
2012, commencing at or about the hour of
10:30 a.m.

1 APPEARANCES OF COUNSEL:

2 FOR THE OPPOSER:

3 HARVEY FREEDENBERG, ESQUIRE
4 McNees, Wallace & Nurick, L.L.C.
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16 ---

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1 FREEDENBERG - BELLER (DIRECT EXAMINATION)

2 THOMAS CHARLES BELLER, M.D.,
3 having been produced and first duly sworn as a
4 witness, testified as follows:

5 DIRECT EXAMINATION

6 BY MR. FREEDENBERG:

7 Q Could you state your full name and your
8 business address for the record, please.

9 A Thomas Charles Beller. My business
10 address is 60 Main Street, Suite D, Hilton Head
11 South, Carolina, 29926.

12 Q Dr. Beller, my name is Harvey
13 Freedenberg.

14 As you know, I'm an attorney
15 representing Mylan Incorporated in a trademark
16 proceeding in which an entity with which you're
17 involved, Beaufort County Allergy, is the
18 respondent or the trademark applicant. Have you
19 ever had your deposition taken before?

20 A I've been deposed for other -- you
21 know, for -- not for cases concerning myself.

22 Q Okay.

23 A But for cases of like workman's
24 compensation, things like that.

25 Q Okay. So you've testified in

1 **FREEDENBERG - BELLER (DIRECT EXAMINATION)**
2 e-mail, an attachment that I received from Mr.
3 Verna on Friday afternoon.

4 The first page is an e-mail that you
5 sent to him on January 15th, a covered e-mail,
6 and the second page, which you have the document
7 open to, is something called pertinent timeline
8 involving Epi-Key trademark, is that correct?

9 A Yes.

10 Q Did you prepare this timeline?

11 A Yes, I did.

12 Q Now, you had mentioned, in your
13 previous answer, that you, referring to this,
14 might refresh your recollection about when TCB
15 Medical Devices was formed. Does it, in fact,
16 do that?

17 A Let me see. You know, I'm going to say
18 I -- as far as I recall it was February 2010, if
19 it wasn't it might have been March but it was
20 somewhere right in that timeline.

21 Q Okay. And if you look at the -- I
22 guess the fourth entry from the bottom, it's
23 dated 2-15-10, it says; e-mailed, Mark Foreman.

24 A Yes.

25 Q Now, a large shareholder in TCB Medical

1 **FREEDENBERG - BELLER (DIRECT EXAMINATION)**

2 A I'm not sure I understand your
3 question.

4 Q What were you -- in creating this
5 timeline, what were you trying to capture?

6 A I was trying to let you know exactly
7 how the whole thing evolves. I prepared the
8 timeline for Anthony to pass it on to you.

9 Q Okay, all right. You're obviously
10 familiar with the device called the Epi-Key?

11 A Yes, sir.

12 Q Okay. What is it?

13 A It's a key-shaped device that contains
14 epi.

15 Q And when you use the term "epi" you're
16 referring to epinephrine?

17 A Yes.

18 Q What's the purpose of the device?

19 A It's for patients to carry who are at
20 risk of anaphylaxis.

21 Q Okay. And what is anaphylaxis?

22 A It's a severe allergic reaction.

23 Q Okay. And what are some of the causes
24 of anaphylaxis?

25 A Food allergy, insect allergy, allergy

1 **FREEDENBERG - BELLER (DIRECT EXAMINATION)**
2 Devices about potentially investing in my
3 product -- project; that's the same Mark Foreman
4 that you mentioned a few minutes ago?

5 A Yes.

6 Q What's his business or profession?

7 A He's a software consultant.

8 Q Is he a personal friend of yours?

9 A Yes.

10 Q Is there any legal relationship or
11 business relationship between TCB and we'll call
12 BCA, Beaufort County Allergy?

13 A No, only that they're both related to
14 me and I control and own both companies.

15 Q Okay. Did you prepare the chronology
16 that's on the second page of Exhibit 2 about the
17 time that you sent it to Mr. Verna in the middle
18 of January?

19 A Do you mean did I prepare this
20 timeline?

21 Q Yes.

22 A Yes.

23 Q Does this timeline set forth the
24 significant dates relating to the development of
25 the Epi-Key trademark?

1 **FREEDENBERG - BELLER (DIRECT EXAMINATION)**
2 shot reactions, idiopathic exercise-induced.

3 Q What was the reason for developing this
4 device?

5 A Well, because I treat patients who are
6 at risk of this condition --

7 Q Uh-huh.

8 A -- I recognize that there's a big
9 market for these devices and I thought I could
10 have some financial gain.

11 Q Okay. When did that idea first occur
12 to you?

13 A 2008.

14 Q Okay. If you look at the timeline,
15 that's the first entry where it says you
16 conceptualized the idea of making a smaller
17 device to contain epi that could attach to a key
18 chain, is that correct?

19 A Yes, sir.

20 Q Is that the time period, 2008, when you
21 came up with this name, Epi-Key?

22 A Probably.

23 Q And it says in that first entry that
24 you shared your idea, verbally, with a Twinject
25 rep, who is Twinject?

1 FREEDENBERG - BELLER (DIRECT EXAMINATION)

2 Q Okay. But he doesn't have any medical
3 background -- has he ever worked on designing a
4 medical device, to your knowledge?

5 A Well, other than this one.

6 MR. VERNA: Objection, relevancy.

7 THE WITNESS: He did help develop
8 this device, you know, as far as how
9 should it function, you know, where
10 should the safety buttons go, that kind
11 of thing.

12 BY MR. FREEDENBERG:

13 Q Okay. My question was, other than this
14 device has he ever worked on --

15 A No, other than this device, no.

16 Q There's another name listed below Mr.
17 Foreman as Matthew Morton.

18 A Yes.

19 Q Who's Matthew?

20 A He works for TriE Medical. He was one
21 of the engineers.

22 Q And what was his role?

23 MR. VERNA: Objection -- can I
24 preserve an objection over everything?
25 I'm going to --

1 FREEDENBERG - BELLER (DIRECT EXAMINATION)
2 few weeks ago, December 29th 2011.

3 Were you aware that this application
4 had been published sometime after December of
5 last year?

6 A You know, my understanding was we
7 initially filed a -- you know, there's a new
8 category of patents that you have one year to
9 change it, I forget the exact name.

10 Q Does the term "provisional patent" --

11 A Provisional, yes. So we initially
12 filed a provisional patent I believe in 2010.

13 Q If you look at the first page of the
14 application, I'll direct your attention to
15 something there. Do you see where it says;
16 related U.S. application data?

17 A Yes.

18 Q And it says; professional application,
19 and then there's a number filed on --

20 A Yes.

21 Q -- June 23rd?

22 A Yes.

23 Q So that's consistent with your
24 recollection?

25 A Yes, absolutely.

1 FREEDENBERG - BELLER (DIRECT EXAMINATION)

2 MR. FREEDENBERG: Sure.

3 MR. VERNA: I'm going to object to
4 everything on this exhibit as
5 irrelevant so we'll just not waste our
6 time.

7 MR. FREEDENBERG: Okay, thanks.

8 MR. VERNA: Go ahead.

9 THE WITNESS: So Matt is one of
10 the engineers. You know, when I
11 mentioned, on the timeline, that I
12 contacted TriE Medical, he's one of the
13 engineers that works for TriE Medical.

14 BY MR. FREEDENBERG:

15 Q Again, we'll get back to TriE Medical
16 in a little bit.

17 And would that also be true of Amanda,
18 if I'm pronouncing this correctly, Bedsaul.

19 A Yes.

20 Q She's also an engineer with TriE?

21 A Yes.

22 Q Looks like this application was filed
23 on June 23, 2011. And from the information we
24 have if you go to the actual application,
25 itself, it looks like it was published just a

1 FREEDENBERG - BELLER (DIRECT EXAMINATION)

2 Q And then do you recall that there was a
3 formal patent application filed a year later?

4 A Yes.

5 Q And then, according to this
6 information, that application was published on
7 December 29th 2011?

8 A Okay.

9 Q Now, if you would, look, you can skip
10 over the drawings. Do you recall reviewing this
11 patent application before it was filed?

12 A Yes.

13 Q Okay. If you go to the section of the
14 application, it's entitled, Background of the
15 Invention; do you see that?

16 MR. VERNA: Right there.

17 THE WITNESS: Yes.

18 BY MR. FREEDENBERG:

19 Q If you go to the -- there are numbered
20 paragraphs here, which makes it easier to refer
21 to, but if you look at paragraph 0005.

22 A Uh-huh.

23 Q I'm going to read the page -- sentence
24 to you, actually two sentences and ask if you
25 agree with these two sentences; The most common

1 **FREEDENBERG - BELLER (DIRECT EXAMINATION)**
2 automatic emergency epinephrine injector
3 apparatus is the EPI-PEN -- that word is all
4 capped and then there's an R in a circle
5 following that -- auto-injector distributed by
6 Mylan Inc. I'll stop at that, do you agree with
7 that statement?

8 A Yes.

9 Q Second sentence says; The EPI-PEN,
10 again all capped with the R in the circle,
11 injector is designed to rapidly inject an adult
12 dose of about 0.30 milligrams of epinephrine. Do
13 you agree with that statement?

14 A Yes.

15 Q The spelling of epinephrine is
16 e-p-i-n-e-p-h-r-i-n-e.

17 If you go to the paragraph labeled
18 0006, which is in the second column of the first
19 page.

20 A Uh-huh.

21 Q I'll read that statement to you, I'll
22 read it for the record and then ask if you
23 agree.

24 "It would be desirable to provide a
25 more compact, easier to use injector which

1 **FREEDENBERG - BELLER (DIRECT EXAMINATION)**
2 of the patent?

3 A Well, when you say 'talked to about
4 potential license', I mean we certainly never
5 sat down and said, 'We're going to make an
6 agreement' but we presented our idea with the
7 hopes of making an agreement. We spoke with --
8 I mean I still have all their business cards at
9 home.

10 Q Uh-huh.

11 A John Wilmot is the name that comes to
12 mind.

13 Q Can you spell, W-i-l-m --

14 A M-o-t.

15 Q -- m-o-t?

16 A W-i-l-m-o-t.

17 Q Okay.

18 A He's with Meridian. He was the main
19 person we communicated with.

20 My initial contact was at Mylan and his
21 name was Drew, I think his full name is Andrew,
22 it's either Cuney or McCuney, I can't remember.

23 Q Okay.

24 A I think it's Cuney.

25 Q C-o-o-n-e-y?

1 **FREEDENBERG - BELLER (DIRECT EXAMINATION)**
2 patients are more likely to carry on their
3 person for rapid transcutaneous administration
4 of a predetermined dose of medication. It would
5 also be desirable to provide an injector which
6 can be unlocked, activated and administered with
7 the use of only one hand."

8 Is that -- do you believe that's an
9 accurate statement in describing your Epi-Key
10 auto injector?

11 A Yes.

12 Q And were those at least some of the
13 advantages that you believed existed or believe
14 existed in this device over other devices?

15 A Yes.

16 Q Have you had any discussions with any
17 third parties about licensing the patent if and
18 when it eventually issues?

19 A Yes.

20 Q Who have you talked to about that?

21 A Every one associated with EpiPen, so
22 Mylan, King, Meridian. We also had discussions
23 with was it Alo -- ALK Abello.

24 Q Okay. Do you recall who you have
25 talked to at Mylan about the potential license

1 **FREEDENBERG - BELLER (DIRECT EXAMINATION)**

2 A I think it's C-u-n-e-y but I'm not
3 positive.

4 Q Okay. Did you ever meet with Mr. Cuney
5 or Mr. Wilmot?

6 A Yes.

7 Q Where did the meetings take place?

8 A First meeting took place in Connecticut
9 at King Pharmaceutical's offices.

10 Q Okay. And who was present at that
11 meeting?

12 A Well, John --

13 MR. VERNA: Objection, again, on
14 relevance to this entire -- can we
15 preserve that for this entire line
16 then?

17 MR. FREEDENBERG: Uh-huh, sure.

18 MR. VERNA: Okay.

19 THE WITNESS: So Drew Cuney, John
20 Wilmot, the President of -- I'm trying
21 to think who was the company that --
22 Dey.

23 BY MR. FREEDENBERG:

24 Q Dey?

25 A Dey Pharmaceuticals.

1 FREEDENBERG - BELLER (DIRECT EXAMINATION)
 2 **MR. FREEDENBERG:** In other words,
 3 you can tell me and I'm not --
 4 **THE WITNESS:** You're not going to
 5 go tell Meridian and Mylan what I said?
 6 **BY MR. FREEDENBERG:**
 7 **Q No, no.**
 8 **A Yeah, we considered Medi Key.**
 9 **Q M-e-d-i?**
 10 **A M-e-d-i-Key, Allergi-Key.**
 11 **Q Okay. A-l-l-e-r-g-i?**
 12 **A Yeah.**
 13 **Q And these have hypens in them?**
 14 **A In both, Allergy, as well --**
 15 **Q Okay.**
 16 **A -- hyphen Key.**
 17 **Q Any others?**
 18 **A Adrena-Key.**
 19 **Q Okay. Is that it?**
 20 **A That's it.**
 21 **Q Did you do trademark searches for any**
 22 **of those names or ask anyone to do searches for**
 23 **them?**
 24 **A Nothing official. I may have searched**
 25 **Google but nothing beyond that.**

1 **FREEDENBERG - BELLER (DIRECT EXAMINATION)**
 2 **A Sometimes, yes, and if I think of it I**
 3 **try and train them as often as possible.**
 4 **Q What's the risk of someone not being**
 5 **trained in using the device?**
 6 **MR. VERNA:** Objection, relevancy.
 7 **THE WITNESS:** That they use it
 8 improperly.
 9 **BY MR. FREEDENBERG:**
 10 **Q And if they use it improperly, then the**
 11 **device may not serve its intended purpose?**
 12 **A Exactly.**
 13 **Q And I assume when people are prescribed**
 14 **this device they may go many months or years**
 15 **without ever having to use it unless they --**
 16 **A Correct.**
 17 **Q -- have a situation where they need it,**
 18 **correct?**
 19 **A Yes.**
 20 **Q Do you have or have you, in your**
 21 **practice, ever prescribed any other epinephrine**
 22 **auto injectors other than EpiPen?**
 23 **A Yes.**
 24 **Q The EpiPen auto injector?**
 25 **A Yes.**

1 **FREEDENBERG - BELLER (DIRECT EXAMINATION)**
 2 **Q You're obviously familiar, in your**
 3 **practice, as an allergist, with the EpiPen**
 4 **injector?**
 5 **A Yes.**
 6 **Q Is that a device that you prescribe for**
 7 **your patients?**
 8 **A Yes.**
 9 **Q And would you agree that for someone**
 10 **who is at risk of anaphylaxis, that this can be**
 11 **a lifesaving device?**
 12 **A Yes.**
 13 **Q When you prescribe this device, did you**
 14 **train, you or someone on your staff train your**
 15 **patients in how to use it?**
 16 **A Yes.**
 17 **Q Describe that training for me.**
 18 **A I have a training device. I show them**
 19 **you pull off the safety, the button goes against**
 20 **the leg, press, click, count to ten. Then I**
 21 **have the patient demonstrate back to me.**
 22 **Q Is it necessary to train someone more**
 23 **than once on it? I mean when they come back for**
 24 **periodic visits, for example, do they have to do**
 25 **it again?**

1 **FREEDENBERG - BELLER (DIRECT EXAMINATION)**
 2 **Q Which ones?**
 3 **A Twinject and a generic device, you**
 4 **know. It -- I don't really know what the name**
 5 **of it is, I think it's just called generic**
 6 **epinephrine auto injector.**
 7 **Q Okay.**
 8 **A It was made by Greenstone and I'm not**
 9 **sure that it's still available but it would also**
 10 **be autoswitched if you write Adrenaclick.**
 11 **Q I was going to ask you if you've ever**
 12 **heard of that device.**
 13 **A Yes.**
 14 **Q What's Adrenaclick?**
 15 **A It's a Twinject without the second**
 16 **injection.**
 17 **Q And who's the manufacturer of the**
 18 **Twinject injector, the Adrenaclick?**
 19 **A I believe it's now -- used to be**
 20 **Sciele. I think it's now Shionogi.**
 21 **Q Do the Twinject and the Adrenaclick**
 22 **auto injectors operate differ -- differently**
 23 **from the EpiPen auto injector?**
 24 **A Slightly.**
 25 **Q And what -- describe in what way.**

FREEDENBERG - BELLER (DIRECT EXAMINATION)

A The Twinject and Adrenaclick both have two covers that need to be removed, so there's a cover over the needle portion of the device which is not present in the EpiPen device.

Q Okay. Anything else?

A Well, the Twinject device, once you've fired the first auto injection you can unscrew the top, take out the syringe and manually inject the second injection.

Q Okay. And that would be if a second injection is needed?

A Correct.

Q When you have prescribed those, those auto injectors in the past, do you also train --

A Yes.

Q -- patients in how to use those?

A Yes.

Q Today, what percentage of your patients are prescribed -- if any, are prescribed the EpiPen auto injector?

A 99 percent.

Q Has that been true in the six or seven years that you've been in practice?

A No.

FREEDENBERG - BELLER (DIRECT EXAMINATION)

Numbers 6 and 7 were marked for identification.)

BY MR. FREEDENBERG:

Q Okay. Dr. Beller, I've put before you a document we've marked as Exhibit 6.

Exhibit 6 is a document entitled, Applicant's Answers to Opposer's First Set of Interrogatories. Do you see that?

A Yes.

Q Have you seen this document before today?

A Yes.

Q Were you consulted in preparing the answers to interrogatories?

A Yes.

Q Okay. If you would take a look, please, at Exhibit -- or I'm sorry, excuse me, Interrogatory Number 29.

The other thing I'm going to ask you to do, if you would, is take a look at Exhibit 7, which is the answer to the Notice of Opposition that was filed on behalf of Beaufort County Allergy.

If you go to page two of that document,

FREEDENBERG - BELLER (DIRECT EXAMINATION)

Q Was it 11?

A There was one point when I prescribed virtually 100 percent Twinject.

Q Okay. And what was the reason for moving over to the EpiPen injector?

A Availability.

Q Okay.

A I just became frustrated with the pharmacies calling me and saying, 'We just don't have any right now, we have EpiPen.'

Q Okay. Do patients ever come in and ask for one device or the other if they're familiar with what these devices do?

A No.

Q The Epi Key device that you have developed, you've said that that's intended and it's in the patent application it's intended to be an alternative to the EpiPen auto injector, is that correct?

A Yes.

Q Is it also intended as an alternative to the Twinject or the Adrenaclick injector?

A Yes.

(Whereupon, Defendant's Exhibit

FREEDENBERG - BELLER (DIRECT EXAMINATION)

please, and specifically under the heading, "Applicant's Application Will Not Cause Confusion." Do you see that?

A Yes.

Q Were you involved in formulating any of the reasons that are set forth under that heading as to why Beaufort County Allergy believes that there will not be confusion between Epi-Key and EpiPen?

A In discussions, yes, but I didn't write the document, but yeah, in discussions, yes.

Q It was written by Mr. Verna --

A Yes.

Q -- or someone in his office?

If you look at -- I'll read to you paragraph number five, it says; EpiPen, words are in quote; "EpiPen" has become a colloquial, common generally accepted term for any epinephrine auto injectors. And then there's a footnote to wikipedia and I apologize for making you jump back and forth but these are related.

If you look at answer to Interrogatory Number 29, do you have that in front of you?

A Yes.

1 **FREEDENBERG - BELLER (DIRECT EXAMINATION)**
2 **shareholder and you're 42 percent and then some**
3 **family members have chipped in the rest?**

4 A Correct.

5 **Q Who are the officers of that company?**

6 A Myself and Mark Foreman.

7 **Q Okay. You said that Mr. Foreman is a**
8 **software consultant. What type of work does he**
9 **do, generally?**

10 A I know very little about it but I know
11 he works with software like Oracle, you know,
12 and he primarily consults with Campbell Soup
13 Company, so, you know, that's really all I know.
14 I'm not a software person so that's the extent
15 of my knowledge of what he does.

16 **Q Where is he located?**

17 A In New York. Actually he lives in
18 Phili now.

19 **Q And he's an -- he was acquaintance of**
20 **yours or a friend of yours?**

21 A He and I went to college together.

22 **Q Okay. In looking at exhibit -- well,**
23 **before we get to Exhibit 20, did Mr. Foreman**
24 **immediately respond to this indicating he was**
25 **interested in getting in on the ground floor of**

1 **FREEDENBERG - BELLER (DIRECT EXAMINATION)**
2 **this project, so to speak?**

3 A Yes.

4 **Q Exhibit 20 is the -- an e-mail that you**
5 **sent to some family members?**

6 A Correct.

7 **Q For the record we need to identify**
8 **these people, so who are Bob and Karen Beller?**

9 A My mom and dad.

10 **Q And Bob Beller is the same Bob Beller?**

11 A My brother, Bob.

12 **Q And then there is a C -- I just have an**
13 **e-mail address.**

14 A CGRI, oh, C.

15 **Q Cbell8040@aol.com.**

16 A That's my sister, Cheri.

17 **Q Okay.**

18 A C-h-e-r-i.

19 **Q And Jim is another brother?**

20 A That's my brother.

21 **Q Okay. Did all of your family members**
22 **who were approached --**

23 A Contribute?

24 **Q Yes.**

25 A Yes.

1 **FREEDENBERG - BELLER (DIRECT EXAMINATION)**

2 **Q Okay. And finally, Exhibit 21 was an**
3 **e-mail you sent to a Kevin G.**

4 A Kevin is my brother-in-law. Krg is his
5 initials, I guess.

6 **Q Okay. And what's his last name?**

7 A Grenier, G-r-e-n-i-e-r?

8 **Q What does he do?**

9 A He's an architect.

10 **Q Okay. And David Mellor, M-e-l-l-o-r?**

11 A That's my father-in-law.

12 **Q Did they also contribute?**

13 A Kevin did not but we decided to gift
14 him one percent, so we kicked in his one
15 percent, but Dave, my father-in-law, and Meg, my
16 mother-in-law, yeah, they jointed.

17 **Q Have any of these folks, other than Mr.**
18 **Foreman, have anything more than a passive role**
19 **in this project?**

20 A No.

21 **Q Has TCB Medical Devices done or**
22 **commissioned any type of marketing surveys to**
23 **determine what the sales potential would be for**
24 **this device?**

25 A No.

1 **FREEDENBERG - BELLER (DIRECT EXAMINATION)**

2 **Q Has anyone on your behalf or on behalf**
3 **of the company done any such surveys?**

4 A No.

5 **Q What's your understanding of how the**
6 **device would be sold? Where would the device be**
7 **sold?**

8 A It would be marketed like any drug to
9 physicians.

10 **Q Okay. And dispensed through physicians**
11 **-- through prescriptions and physicians offices?**

12 A Through prescriptions and dispensive
13 pharmacies.

14 **Q Have you had any discussion with anyone**
15 **about preparing any type of marketing materials**
16 **that would be used in connection with the sale?**

17 **MR. VERNA:** Objection, asked and
18 answered.

19 **THE WITNESS:** No.

20 **BY MR. FREEDENBERG:**

21 **Q And would it be fair to say that**
22 **you haven't -- when I say "you" I'm referring to**
23 **TCB hasn't spent any money on developing such**
24 **materials, any marketing materials?**

25 A We have not.

EXHIBIT 11

Like 3k

EpiPen medical definition

A trademark for a self-injection kit containing epinephrine, used intramuscularly for anaphylactic shock.

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Feedback

EXHIBIT 12

An A-Z of Medicinal Drugs

[◀ adrenaline ▶](#)

CROSS-REFERENCE

PRINT THIS ENTRY

EMAIL THIS ENTRY

In this entry

adrenaline

Side effects:

Interactions with
other drugs:

Proprietary
preparations:

See also

adrenoceptors

anaphylaxis

arrhythmia

glaucoma

local anaesthetics

prescription

Adjacent entries

Adenoscan

adenosine

Adipine MR, Adipine

XL

Adizem-XL, Adizem-

SR

adjunct

adrenaline

adrenoceptors

Adult Meltus Chesty

Coughs with

Congestion

Advagraf

aerosol

Afinitor

adrenaline (epinephrine) A hormone that is secreted by the centre (medulla) of the adrenal glands into the bloodstream in conditions of stress. It acts on adrenoceptors to cause constriction of some blood vessels and dilatation of others, increasing blood flow to the heart and skeletal muscles. The heart rate is increased, while the muscles of the intestine and airways relax. As a drug, adrenaline is available in various forms on prescription only. It is given by intramuscular injection to relieve the effects of anaphylactic shock (an extreme and potentially fatal allergic reaction; see anaphylaxis) and by intravenous injection to treat cardiac arrest. It is given with local anaesthetic preparations because it constricts blood vessels and thus confines the local anaesthetic to the area of application. It is also available as eye drops to treat glaucoma, in which it reduces the production of aqueous fluid in the eye and increases its outflow.

Side effects:

when adrenaline is given by injection side effects include dry mouth, palpitation, cold hands and feet, nervousness, tremor, and headache; there may be stomach pain after inhalation. Side effects with eye drops include smarting and redness of the eye and headache.

Interactions with other drugs:

Anaesthetics:

irregular heartbeats (arrhythmias) may occur if adrenaline is given with certain anaesthetics. **Antidepressants:**

hypertension (raised blood pressure) and arrhythmias may occur if

adrenaline is given with tricyclic antidepressants. **Beta blockers:**

severe hypertension may occur if these drugs are given with

adrenaline. **Clonidine:**

hypertension may occur if this drug is given with adrenaline. **Dopexamine:**

may increase the effects of adrenaline. **Entacapone:**

may increase the effects of adrenaline. **Rasagiline:**

should not be used with adrenaline.

Proprietary preparations:

Anapen and Anapen Junior (disposable pens for self-injection); Epipen and Epipen Junior (disposable pens for self-injection); Minijet Adrenaline (injection).

How to cite this entry:

"adrenaline" *An A-Z of Medicinal Drugs*. Ed Elizabeth Martin. Oxford University Press 2010



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EXHIBIT 13

Oxford Reference Online Premium

A Dictionary of Dentistry

EpiPen® (Trade name) *n.* A preassembled syringe containing 300 micrograms of adrenaline for intramuscular injection carried by patients at risk of anaphylaxis for self or third-party injection.

How to cite this entry:

"EpiPen®" *A Dictionary of Dentistry*, by Robert Ireland. Oxford University Press 2010. *Oxford Reference Online*. Oxford University Press. Free Library of Philadelphia. 6 December 2011 <<http://www.oxfordreference.com/views/ENTRY.html?subview=Main&entry=t305.e1463>>

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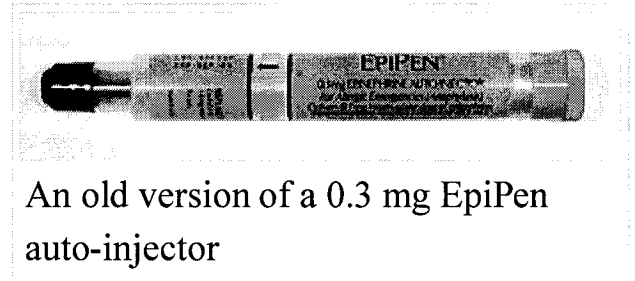


EXHIBIT 14

Epinephrine autoinjector

From Wikipedia, the free encyclopedia

An **epinephrine autoinjector** is a medical device used to deliver a measured dose (or doses) of epinephrine (also known as adrenaline) using autoinjector technology, most frequently for the treatment of acute allergic reactions to avoid or treat the onset of anaphylactic shock.



An old version of a 0.3 mg EpiPen auto-injector

Trade names for this device include **EpiPen**, **Twinject**, **Adrenaclick**, **Anapen**, **Jext**, and **Auvi-Q**. The EpiPen was originally derived from the ComboPen, a product developed for the military for treating exposure to nerve agents.^[1]

Contents

- 1 Design
- 2 Usage
- 3 Effectiveness
- 4 See also
- 5 Notes
- 6 References
- 7 External links

Design

The devices contain a spring-loaded needle that exits the tip of the device (in some cases through a sterile membrane) and into the recipient's body to deliver the medication.

Epinephrine autoinjectors contain a pre-determined dose of epinephrine, usually between 300 µg^{[2][3]} and 500 µg^{[2][4]} of active ingredient at a concentration of 1:1000. They typically contain more medication than the amount needed for a single dose, but any extra amount is not intended for use and is inaccessible without destroying the device. Manufacturers have also made pediatric dosed versions available at 150 µg of active ingredient,^{[2][5]} and there is also a version which contains two individual doses (in case a repeated application is required) sold under the trade name Twinject.^[6]

On August 13th, 2012, the US FDA approved a new version of epinephrine auto-injector made by Intelliject and Sanofi called the Auvi-Q.^[7] It is rectangular in shape, 3.5 inches by 2 inches by 0.5 inch. It has a soundchip in it to give audio cues to a patient or caregiver to aid in the proper use of the device.^[8]

In most countries, epinephrine is a prescription drug, and therefore obtaining the device requires a prescription from a doctor. However, in some jurisdictions, epinephrine autoinjectors are an over-the-counter drug and may be purchased from a pharmacy counter.

Usage

After activation the patient holds the device in place for 10 seconds as the epinephrine is delivered. This gives the drug enough time to be absorbed by the body's muscles and diffused into the bloodstream. Using the device intravenously is highly discouraged, and can even be lethal as epinephrine is a local vascular constrictor, and used intravenously can restrict blood flow to the area of the injection site, causing subsequent damage to extremities. Additionally, intravenous administration of the epinephrine can cause ventricular tachycardia, or dangerously rapid heartbeat.^[9] After administering the device, patients are advised to seek immediate medical attention.

Effectiveness

None of these devices prevent future episodes of anaphylaxis, but patients who experience severe or life-threatening reactions may be treated with a series of allergy injections composed of increasing concentrations of naturally occurring substances such as venom to provide excellent and usually lifelong protections against adverse effects of future insect stings: the initial injections have a very low concentration, usually 1 ppb or less.^[10]

On May 8, 1998, a voluntary Class I recall took place in a number of countries (the United States, Germany, Israel, Denmark, Canada, Turkey, Australia, Greece and South Africa). Epipen (0.3 mg) and Epipen Jr. (0.15 mg) epinephrine auto-injectors were recalled because certain devices originating from specific production lots were found to be ineffective in delivering medication and treating anaphylaxis.^[11] This issue was resolved within the same year.

See also

- Anaphylaxis

Notes

- [^] "EpiPen inventor helped millions and died in obscurity" (<http://www.tampabay.com/news/humaninterest/epipen-inventor-helped-millions-and-died-in-obscurity/1038756>) . St. Petersburg Times. <http://www.tampabay.com/news/humaninterest/epipen-inventor-helped-millions-and-died-in-obscurity/1038756>. Retrieved 2010-07-07.
- [^] ^a ^b ^c "Epipen and Epipen Jr; Dosing | Epinephrine Dose | Anaphylaxis" (http://www.epipen.com/epipen_dosing.aspx) . EpiPen. http://www.epipen.com/epipen_dosing.aspx. Retrieved 2010-07-07.
- [^] "Anapen 300 product information sheet" (<http://www.anapen.co.uk/downloads/SUMMARY%20OF%20PRODUCT%20CHARACTERISTICS%20ANAPEN%20300.doc>) . Lincoln Medical Ltd. <http://www.anapen.co.uk/downloads/SUMMARY%20OF%20PRODUCT%20CHARACTERISTICS%20ANAPEN%20300.doc>.

4. ^ "Anapen 500 product information sheet" (<http://www.anapen.co.uk/downloads/SUMMARY%20OF%20PRODUCT%20CHARACTERISTICS%20ANAPEN%20500.doc>) . Lincoln Medical Ltd. <http://www.anapen.co.uk/downloads/SUMMARY%20OF%20PRODUCT%20CHARACTERISTICS%20ANAPEN%20500.doc>.
5. ^ "Anapen 150 product information sheet" (<http://www.anapen.co.uk/downloads/SUMMARY%20OF%20PRODUCT%20CHARACTERISTICS%20ANAPEN%20150.doc>) . Lincoln Medical Ltd. <http://www.anapen.co.uk/downloads/SUMMARY%20OF%20PRODUCT%20CHARACTERISTICS%20ANAPEN%20150.doc>.
6. ^ Verus Pharmaceuticals Announces U.S. Launch of Twinject for Anaphylaxis (http://www.veruspharm.com/news_releases_08_16_2005.htm)
7. ^ "Sanofi Announces FDA Approval for Auvi-Q" (http://en.sanofi.com/Images/30999_20120813_EAI_FDA_APPROVAL_en.pdf
http://en.sanofi.com/Images/30999_20120813_EAI_FDA_APPROVAL_en.pdf. Retrieved 18 August 2012.
8. ^ "Auvi-Q Fact Sheet" (<http://www.multivu.com/assets/57459/documents/Auvi-Q-Fact-Sheet-original.pdf>) .
<http://www.multivu.com/assets/57459/documents/Auvi-Q-Fact-Sheet-original.pdf>. Retrieved 18 August 2012.
9. ^ <http://www.bmj.com/cgi/content/full/326/7389/589>
10. ^ Resiman, R (August 1994). "Insect Stings". *New England Journal of Medicine* **26**: 523–7. doi:10.1056/NEJM199408253310808(<http://dx.doi.org/10.1056/2FNEJM199408253310808>). PMID 8041420 (<http://www.ncbi.nlm.nih.gov/pubmed/8041420>) .
11. ^ [1] (<http://www.fda.gov/MEDWATCH/safety/1998/epipen.htm>)

References

- The Anaphylaxis Campaign (<http://www.anaphylaxis.org.uk/information/adrenaline.html>) . Accessed on March 19, 2007.
- BMJ Clinical Review of Epinephrine Administration (<http://www.bmj.com/cgi/content/full/326/7389/589>) . Accessed on March 19, 2007.

External links

- US EpiPen information (<http://www.epipen.com/>)
- US Twinject information (<http://www.twinject.com/>)

- US Adrenaclick information (<http://www.adrenaclick.com/>)
- Anapen website (<http://www.anapen.com/>)
- Training video for EpiPen and Anapen from the Anaphylaxis Campaign (UK) (<http://www.anaphylaxis.org.uk/information/health-professionals/administering-adrenaline.aspx>)
- Twinject training video (<http://www.twinject.com/injector-allergy-treatment/twinject-injector-training.html>)

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Categories: First aid | Drug delivery devices

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EXHIBIT 15

Oxford English Dictionary | The definitive record of the English language

EpiPen, *n.*

Pronunciation: Brit. /'ɛpi,pɛn/, U.S. /'ɛpi'pɛn/

Etymology: < *epi* - (in EPINEPHRINE *n.*) + PEN *n.*²

Med.

A proprietary name for: a hypodermic device that administers a dose of epinephrine, used for the emergency treatment of anaphylaxis.

- 1979 *Official Gaz.* (U.S. Patent Office) 5 June TM7/2 *EpiPen*. . . For hypodermic injectors.
- 1989 *N.Y. Times Mag.* 2 July 28/4 Although I have no allergies, I usually bring along an EpiPen when I travel to the countryside, a practice I always attributed to paranoia.
- 1996 *Independent* (Nexis) 7 Sept. 11 His next attack, again caused by peanut butter, came at a birthday party when he was three. . . He travels with an EpiPen which can be used to deliver a life-saving adrenalin injection.
- 2003 A. HOFFMAN *Probable Future* 259 He was so allergic, Liza had convinced him to carry an EpiPen in his pocket when he went out running, in case he met up with a bee.

EpiPen, *n.*

Third edition, August 2006; online version September 2011. <<http://www.oed.com/view/Entry/262201>>; accessed 06 December 2011.

Oxford University Press

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EXHIBIT 16

[Citation](#) [HTML Full Text](#)[Print](#) [E-mail](#) [Save](#)

Title: *Epinephrine*. Lexi-PALS Drug Guide, Nov2011

Database: *Consumer Health Complete*

Epinephrine

En Español (Spanish Version)

Last modified: 03/28/2011

The following information is an educational aid only. It is not intended as medical advice for individual conditions or treatments. Talk to your doctor, nurse or pharmacist before following any medical regimen to see if it is safe and effective for you.

Pronunciation

(ep i NEF rin)

Pharmacologic Category

Alpha/Beta Agonist

U.S. Brand Names

Adrenaclick™ [DSC], Adrenalin®, EpiPen 2-Pak®, EpiPen Jr 2-Pak®, EpiPen®, EpiPen® Jr., Primatene® Mist [OTC], S2® [OTC], Twinject®

Canadian Brand Names

Adrenalin®, EpiPen®, EpiPen® Jr, Twinject®

What key warnings should I know about before taking this medicine?

- This medicine does not mix well with some medicines. Serious reactions may occur. Check all medicines with healthcare provider.

Reasons not to take this medicine

- If you have an allergy to epinephrine or any other part of this medicine.
- Tell healthcare provider if you are allergic to any medicine. Make sure to tell about the allergy and how it affected you. This includes telling about rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other symptoms involved.

Inhaler:

- If you have taken isocarboxazid, phenelzine, or tranylcypromine in the last 14 days. Monoamine oxidase inhibitors (eg, isocarboxazid, phenelzine, and tranylcypromine) must be stopped 14 days before this medicine is started. Taking the two together could cause dangerously high blood pressure.

What is this medicine used for?

- This medicine is used to treat severe allergic reactions.
- This medicine is used to open the airways in lung diseases where spasm may cause breathing problems.
- This medicine is used to treat low blood pressure.
- This medicine is used when the heart is not beating.

How does it work?

Injection:

- EpiPen®, EpiPen® Jr: This medicine blocks the allergic reaction by minimizing or preventing the body's reaction to the allergen.
- Adrenalin®: This medicine excites the heart.

Inhaler:

- This medicine works to open the airways in lung diseases where spasms may cause breathing problems.

How is it best taken?**EpiPen®, EpiPen® Jr:**

- Read directions before an emergency occurs.
- Use this medicine for emergencies which may include insect stings or bites, food, drug, latex allergies, and ones caused by exercise.
- Keep this medicine with you at all times. Can keep extra ones at work, school, and home.
- Never put fingers, or hand over tip.
- Do not remove safety release until ready to use.
- Do not use if solution is not clear or if red flag is in window.
- When ready to use, remove pen from case.
- Hold pen with tip pointing down.
- Make a fist around pen.
- Pull off safety release.
- Jab straight into the outer thigh until it clicks and hold for 10 seconds.
- Remove and massage area where shot was given.
- Get medical attention now.
- Call the emergency department. Do not drive yourself to the hospital.
- Replace in storage case.
- Take it with you to the hospital.

Adrenalin®:

- Your healthcare provider will give this medicine.

Inhaler:

- For inhaling (puffing) only by an inhaler or as a liquid (solution) through a special machine (nebulizer) into the lungs.
- Inhale once, may repeat in 1 minute if symptoms are not relieved. Wait at least 3 hours before using again.

What do I do if I miss a dose? (does not apply to patients in the hospital)

- Many times this medicine is taken on an as needed basis.

What are the precautions when taking this medicine?

- If you have heart disease, talk with healthcare provider.
- If you have thyroid disease, talk with healthcare provider.
- Check medicines with healthcare provider. This medicine may not mix well with other medicines.
- Tell healthcare provider if you are pregnant or plan on getting pregnant.
- Tell healthcare provider if you are breast-feeding.

What are some possible side effects of this medicine?

- Feeling dizzy. Rise slowly over several minutes from sitting or lying position. Be careful climbing.
- Irritation where the shot is given.
- Flushing.
- Nausea or vomiting. Small frequent meals, frequent mouth care, sucking hard, sugar-free candy, or chewing sugar-free gum may help.
- Dry mouth. Frequent mouth care, sucking hard, sugar-free candy, or chewing sugar-free gum may help.
- Nervous and excitable.

What should I monitor?

- Change in condition being treated. Is it better, worse, or about the same?
- Take good care of your teeth. See a dentist regularly.
- Follow up with healthcare provider.

Reasons to call healthcare provider immediately

- If used for allergy emergency, go to an emergency room immediately after use.
- If you suspect an overdose, call your local poison control center or emergency department immediately.
- Signs of a life-threatening reaction. These include wheezing; chest tightness; fever; itching; bad cough; blue skin color; fits; or swelling of face, lips, tongue, or throat.
- Unable to get breathing attack under control. Get emergency medical care right away.
- Fast heartbeat.
- Severe nausea or vomiting.
- Feeling extremely tired or weak.
- Any rash.
- No improvement in condition or feeling worse.

How should I store this medicine?

- Store at room temperature.

EpiPen®, EpiPen® Jr:

- Protect from light.

Primatene® Mist:

- Protect from heat or open flame.

General statements

- If you have a life-threatening allergy, wear allergy identification at all times.
- Do not share your medicine with others and do not take anyone else's medicine.
- Keep all medicine out of the reach of children and pets.
- Most medicines can be thrown away in household trash after mixing with coffee grounds or kitty litter and sealing in a plastic bag.
- In Canada return any unused drugs back to the pharmacy. Also, visit <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/disposal-defaire-eng.php#th> for more facts about the right way to get rid of unused drugs.
- Keep a list of all your medicines (prescription, natural products, supplements, vitamins, over-the-counter) with you. Give this list to healthcare provider (doctor, nurse, nurse practitioner, pharmacist, physician assistant).
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or in Canada to Health Canada's Canada Vigilance Program at 1-866-234-2345.
- Talk with healthcare provider before starting any new medicine, including over-the-counter, natural products, or vitamins.

Please be aware that this information is provided to supplement the care provided by your physician. It is neither intended nor implied to be a substitute for professional medical advice. CALL YOUR HEALTHCARE PROVIDER IMMEDIATELY IF YOU THINK YOU MAY HAVE A MEDICAL EMERGENCY. Always seek the advice of your physician or other qualified health provider prior to starting any new treatment or with any questions you may have regarding a medical condition.

Last modified: 03/28/2011

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EXHIBIT 17



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Title: *EpiPen*. Royal Society of Medicine: Medicines, 2002

Database: *Consumer Health Complete*

EpiPen

EpiPen

(ALK-Abello) is a proprietary, prescription-only preparation of adrenaline acid tartrate (epinephrine). It is used as a and drug in emergency treatment of acute and severe bronchoconstriction and other symptoms of acute anaphylaxis (allergic reaction; eg an insect sting). It is available as an auto-injector, which delivers a single intramuscular dose, and also as a version for children, EpiPen Jr Auto-injector.

See.

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Epinephrine Auto-injectors - Patients May Need Re-training

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Recently, a generic epinephrine auto-injector became available on the market. This may result in pharmacies substituting the generic auto-injector for a brand-name auto-injector, or vice-versa.

If you or someone you know has been prescribed an epinephrine auto-injector, please be aware that specific brand-name epinephrine auto-injectors, such as Adrenaclick™, EpiPen® or Twinject™, as well as the generic version, each have their own unique instructions for proper administration.

Families may have been trained by their pediatricians or allergists on the use of one type of auto-injector, then receive another type from the pharmacy on which they have received no training. It is important to have a clear understanding of the training instructions for the auto-injector obtained at the pharmacy.

For more information on epinephrine auto-injectors, visit the **American Academy of Pediatrics Allergy and Immunology section of the AAP website**. Similar information can be found on the websites of the **American Academy of Allergy, Asthma & Immunology** and the **American College of Allergy, Asthma & Immunology**.

About FAAN

Founded in 1991, The Food Allergy & Anaphylaxis Network (FAAN) is the world leader in information, resources, and programs for food allergy, a potentially life-threatening medical condition that afflicts as many as 15 million Americans including almost 6 million children. A nonprofit organization based in Fairfax, Va., FAAN has approximately 22,000 members in the U.S., Canada, and 58 other countries. It is dedicated to increasing public awareness of food allergy and its consequences, to educating people about the condition, and to advancing research on behalf of all those affected by it. FAAN provides information and educational resources about food allergy to patients, their families, schools, health professionals, pharmaceutical companies, the food industry, and government officials. To become a member or for more information, please visit FAAN at www.foodallergy.org.

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EXHIBIT 19

About.com Food Allergies

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When is an Epi-Pen Not an Epi-Pen?

By Jeanette Bradley, About.com Guide June 24, 2010
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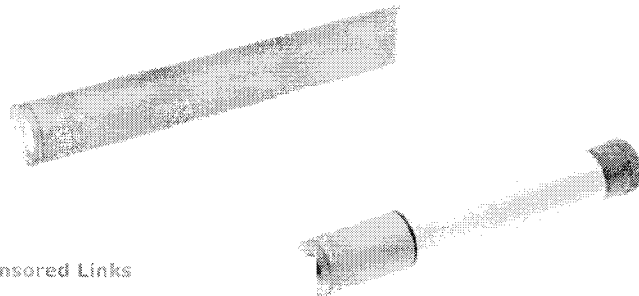
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20 Ways To Stop Allergies

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www.health.com

An Epi-Pen is prescribed as emergency treatment for severe food allergies that include anaphylactic shock as a symptom. Epi-Pen is actually a brand name, like Kleenex. There is now a generic epinephrine auto-injector on the market.

The good news is that generic drugs are less expensive, which is particularly good for people without insurance. Epi-Pens are not cheap, and you need to replace them every year.

The bad news is that the generic auto-injector is different from either of the most commonly prescribed brand names, Epi-Pen and Twinject. Your doctor may have prescribed one of these brand name injectors to you and trained you how to use it. Your pharmacy (or rather, your insurance company) may give you the generic injector instead.

Check your injector to see what brand it is, and then look up the instructions for its use. Ask your doctor to prescribe a "trainer" pen - a fake pen used for educational purposes - with each new prescription.

Having a trainer pen is especially important if you have a child with food allergies who has multiple caregivers - babysitters, grandparents, teachers, and the parents of his friends. Everyone who takes care of your child should be trained how to use his injector.

Instructions for each type of injector:

[Adrenaclick](#) (makers of the generic injector, distributed by Greenstone)

[Epi-Pen](#)

[Twinject](#)

More About Anaphylaxis and Epinephrine:

[First Aid for Anaphylaxis](#)

When is an Epi-Pen Not an Epi-Pen?

[How to Use an Epi-Pen](#)

[Anaphylaxis](#)

[Epinephrine Auto-Injector](#)

Source:

American Academy of Pediatrics. *Availability of Generic Epinephrine Auto-Injector*. Accessed June 23, 2010.
<http://www.aap.org/sections/allergy/new.cfm#new>

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- Glossary

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- Anaphylaxis: What You Need to Know
- Most Common Food Allergies
- Food Allergy Signs and Symptoms
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EXHIBIT 20



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Teen dies after eating cookie containing peanut

By Alexis Stevens
The Atlanta Journal-Constitution

7:46 p.m. Thursday, August 18, 2011

While his aunt shopped Tuesday, 15-year-old Jharell Dillard ran outside to grab a snack from the car. He remembered there were cookies and he grabbed one, his father told the AJC Thursday night.

But the chocolate chip cookie also contained traces of peanuts, sending Jharell's body into shock. Jharell's allergy caused his tongue and throat to swell and restricted his breathing, Charles Dillard said.

The teen was transported Walton County Medical Center Tuesday, then flown Wednesday to Children's Healthcare of Atlanta at Egleston, where he died.

"This was one of those freak accidents," Dillard told the AJC. "He was very, very careful about what he ate."

When he realized the cookie contained nuts, Jharell ran to a nearby McDonald's, where he tried to rinse his mouth out, his father said. The teen also took an over-the-counter allergy medication, but the reaction continued. A family member called 911 and Jharell was transported to the hospital, but it was too late.

Jharell, who was in the 11th grade at Central Gwinnett High School, normally didn't carry an injection of epinephrine, known by the brand name EpiPen, because he was aware of his allergy and generally cautious. After his death, Jharell's parents decided to donate their sons' organs.

"He has already saved seven other lives," his father said.

Jharell was very involved in his church, family friend Roland Pinder told the AJC.

"Jharell was a soft-spoken, low-key kid, but he didn't go unnoticed," Pinder said.

In addition to his parents, Jharell is also survived by two sisters.

Funeral arrangements are tentatively scheduled for Aug. 28 at Stone Mountain Seventh-day Adventist Church.

Find this article at:
<http://www.ajc.com/news/gwinnett/teen-dies-after-eating-1120883.html>

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EXHIBIT 21

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Food allergies can be deadly

By Alexis Stevens
The Atlanta Journal-Constitution

7:16 p.m. Friday, August 19, 2011

Four out of 100 children have a food allergy and the number of those diagnosed continues to rise, experts say.

Though the exact cause of the increase isn't known, children with allergies and their parents must scrutinize food carefully to avoid potentially deadly situations. The death of a 15-year-old metro Atlanta boy this week has made more people aware of the severity of allergies.

Jharell Dillard, an 11th grader at Central Gwinnett High School, was well aware of his peanut allergy and had had a reaction before, his father, Charles Dillard, told the AJC. Jharell, a soft-spoken teen, loved basketball and had NBA dreams, his father said. Had Jharell known the store-bought cookie he took a bite of contained traces of nuts, he wouldn't have eaten it.

"This was one of those freak accidents," Dillard told the AJC. "He was very, very careful about what he ate."

While family, friends, classmates and teachers mourn Jharell's death, others hope the tragedy serves as an eye-opening lesson. Each year, about 150 people die from an allergic reaction to food, according to the Centers for Disease Control.

"Being prepared for accidents is key," Dr. Karen DeMuth, a pediatric allergy and immunology specialist, told the AJC. "You need to know what to do and how to react when you have an accident."

When a person with a food allergy accidentally ingests the allergen, several symptoms can occur, DeMuth said. Skin rashes, swelling, respiratory distress, coughing, wheezing, sneezing and vomiting are all possible, she said.

If a child is having a severe allergic reaction, also called anaphylaxis, there is one treatment: Epinephrine.

The medication, which is injected, is often dispensed under the brand name EpiPen, DeMuth said. Once injected, it works immediately to stop the reaction and lasts only about 10-15 minutes, allowing enough time to make an emergency call to 911, she said.

Having an EpiPen nearby, and knowing how to use, can relieve some of the stress that a food allergy can bring for both parents and children, said DeMuth, who works at both Emory University and Children's

Healthcare of Atlanta.

There is currently no cure for food allergies. But still, many allergy sufferers don't carry the injection, relying instead on the belief that they can avoid the allergen, which may not always be possible. Doctors refer to this as "risk drift," DeMuth said.

"This happens to every one of us," DeMuth said. "You just have to remind yourself every day of why it's so important."

Education about the dangers of food allergies is key to preventing tragedies, such as Jharell's death, according to Aleasa Word, a mother of a child with eight food allergies and an advocate. Word's daughter has twice been the victim of "peanut bullying," where another child has tried to force peanut butter on her daughter's face.

"Kids don't understand that someone could really get sick," Word said.

As the executive director of the Food Allergic Multi-Cultural Society of Delaware, Word said people must realize allergies cross all races. The group plans to reach out to Jharell's family by sending flowers for the teen's funeral, she said.

"People need to understand that this affects everyone," Word said. "We're all one big family with one problem."

Not everyone with food allergies will have a severe reaction, such as the one Jharell suffered. For most people with food allergies, sitting next to someone eating the allergen isn't enough to cause a problem. Soap and water are enough to remove the peanut allergen, DeMuth said.

The Food Allergy Kids of Atlanta group offers support and educational opportunities for families dealing with food allergies.

"There is no way to know how severe a reaction will be," DeMuth said. "If you're being careful and you're prepared, you're in control. You're always ready."

Find this article at:

<http://www.ajc.com/news/food-allergies-can-be-1124064.html>



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EXHIBIT 22

Expert Report from Ray S. Davis, MD

INTRODUCTION:

My name is Ray S. Davis, M.D., and I have been asked to provide an expert witness report in a trademark dispute between Dey Pharmaceuticals, Inc. and Mylan Labs and TCB Medical Devices over the proposed Epi-Key name vs. EpiPen® for autoinjectors. I was asked to give my opinion regarding several issues and concerns which are being addressed in this case from my perspective in practicing as a specialist in clinical allergy and immunology for the past 30 years.

My preparation for this report is based upon 30 years of experience in private practice as a specialist who is board certified in both pediatrics and allergy/immunology and who has seen thousands of patients with food allergies, drug allergies and insect venom allergies and anaphylaxis as well as cases of anaphylaxis of unknown causes (idiopathic). I not only teach regularly as a full Professor in Clinical Pediatrics in the Division of Allergy Immunology and Pulmonary Medicine, St. Louis Children's Hospital, Washington University School of Medicine, St. Louis, Missouri, but I also have lectured all over this country and outside it to other healthcare professionals on these subjects scores of times.

QUALIFICATIONS:

My background is initial training in general pediatrics at Washington University School of Medicine and St. Louis Children's Hospital (1978-1980) followed by specialty training in allergy & immunology at the consistently number 1 ranked respiratory hospital in this country—the National Jewish Hospital/National Asthma Center now called National Jewish Health (1980-1982), www.nationaljewish.org.

I have worked at multiple hospitals and Emergency Rooms in Louisville, Denver & St. Louis. I am a “Fellow” of both the American Academy of Allergy Asthma and Immunology and the American College of Allergy Asthma and Immunology and have been chosen to speak at their annual continuing education meetings (CME) multiple times. I also give many other talks at national and regional CME meetings in my field.

My curriculum vitae is attached to this report. See Exhibit A.

BACKGROUND:

As a pediatric resident in training in the 1970s, the only “kit” available for patients who needed to have aqueous epinephrine available to treat a severe potentially fatal allergic reaction was the Ana-Kit™. This syringe of epinephrine with instructions on how a patient should give a self injection proved to be awkward and difficult for most patients seeing an exposed needle. Despite that, it is still an available choice by prescription today. Thankfully, EpiPen® autoinjector was developed and over the next 3 decades, with its hidden needle and “automatic” injector mechanism, it has become the treatment of choice widely accepted for virtually all patients who need this form of treatment. EpiPen® represents a brand of autoinjector that has been counted upon by most allergists for decades despite attempts to develop other autoinjectors such as Twin-Ject® and AdrenaClick®, each of which has had its problems. Each time a new device was introduced, specialists referred to it by its specific brand name and no one called it an “EpiPen.” Furthermore, when “EpiPen” is prescribed or used in conversation, everyone in the field, as well as patients, understands that it is the original brand of the product made and quality controlled by Mylan Labs. The name EpiPen® is synonymous with a famous brand of epinephrine autoinjector which is unique in its mechanism and has withstood the test of time and many thousands of uses. Although some may claim that “epi” or “epipen” refers to ALL self injectable aqueous epinephrine medications, “EpiPen” stands apart as the brand of choice and **is NOT a generic word for ALL other self injectable epinephrine medications.**

“Epi” or “epipen” should not be confused with the utilization of aqueous epinephrine injectable solutions drawn up at hospitals for intracardiac injections during cardiac arrests. This “epi” given stat (immediately) is either aqueous adrenaline 1:1,000 USP in a sterile vial for intramuscular, subcutaneous or intravenous use or if the “epi” is to be injected into the heart of a dying patient, it is a 1:10,000 concentration called Adrenaline (Epinephrine) 1:10,000 Sterile Solution Minijet™ and is used during codes at most hospitals. In fact, autoinjectors are generally not used in most hospitals or emergency rooms around this country since health care professionals are trained to draw up the correct dose and inject it properly either intracardiac, intravenously, or intramuscularly; they do not need the convenience of the autoinjector, which most patients and lay people do. Thus, what may be referred to as “epi” in a hospital setting should not be confused with an EpiPen® autoinjector.

In teaching a Continuing Medical Education course on food allergies and anaphylaxis at the Eastern Allergy Conference several years ago in Palm Beach, Florida, I presented a real case to a group of over 100 allergy and asthma specialists from all over the U.S. The discussion led to a specific individualized treatment plan for the

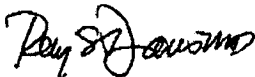
patient and as such, a discussion occurred about whether or not it mattered which brand of epinephrine autoinjector should be recommended. Although some admitted to having tried other brands on some patients in the past for various reasons, the group believed, almost without exception, that the EpiPen® autoinjector was the only device and brand they trusted. In my opinion, from these observations and many others, it is clear that specialists in the field of allergy and immunology do not refer to ALL self-administered epinephrine autoinjectors as “epipens.” If referring to an alternative autoinjector, they specifically mention, e.g., Twin-Ject® or Ana-Kit™, by their brand names.

In my office, at every new patient visit or routine yearly check up for a patient with food allergies or anaphylaxis (or for any other reason), we go over a check list, emphasizing the newly updated Food Allergy and Anaphylaxis Guidelines published in 2010. For all of my patients, I prescribe EpiPen® autoinjectors and no other brands. The proper technique of injection must be demonstrated to my nurses or medical assistants by either the patient or a parent. I would personally hate to think that if I had prescribed an EpiPen® autoinjector, demonstrated the proper technique and the patient received a different device and tried to use it, the confusion could be potentially fatal. Or, if another device had a similar name, such as Epi-Key, there could be confusion by the patient or pharmacist about which device to dispense or use, which again could lead to a fatal result.

CONCLUSION:

EpiPen®, in my opinion, is a famous name brand for a device that dispenses aqueous epinephrine. That device has been utilized for many years by many thousands of patients who need a reliable, life saving device and medication to carry on a daily basis. Among physicians, the trademark is as recognizable as Coke® and iPhone®. There will always be those who attempt to copy others’ work, but the name EpiPen® is unique and should not be generalized to mean, and other device names should not be allowed to be confused with anything but the original device.

Most sincerely,

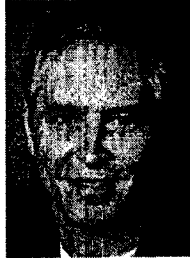


Ray S. Davis, M.D.
Professor in Clinical Pediatrics
Division of Allergy Immunology and Pulmonary Medicine
St. Louis Children’s Hospital
Washington University School of Medicine
And Private Practice with Allergy Consultants, P.C.

EXHIBIT A

CURRICULUM VITAE - Ray S. Davis, M.D.

Date: Nov. 2011



Personal Information:

Sex: Male
Born: January 5, 1953
Place of Birth: Louisville, Kentucky

Citizenship:

United States of America

Address and Telephone Number:

Home: NA
Office: Allergy Consultants
456 North New Ballas Road
Suite 129
St. Louis, MO 63141
314-569-1881(pvt.lines 569-1444 or 1448)
Email ahchu1@aol.com

Present Position:

Private Practice - Allergy Consultants, P.C. (President and Senior partner)

Education:

Undergraduate:

University of Louisville, no degree obtained due to
early acceptance to medical school after 97 credit hours;
grade point average 3.95

Graduate:

5-14-78 M.D.: University of Louisville School of Medicine

CURRICULUM VITAE - Ray S. Davis, M.D.

Postgraduate:

- 6-23-78 to 6-30-79 Internship - Pediatrics, Washington University School of
Medicine, St. Louis Children's 7-1-79 to 6-30-80
Residency -
Pediatrics, Washington University
School of Medicine
St. Louis Children's Hospital
- 7-1-80 to 6-30-82 Fellowship - Allergy/Immunology National Jewish
Hospital and Research Center, the National Asthma
Center, and the University of Colorado Medical Center,
Denver, Colorado

Academic Positions/Employment:

Professor of Clinical Pediatrics, St. Louis Children's Hospital; Washington
University School of Medicine, St. Louis, MO - Division of Allergy and Pulmonary
Medicine, Washington University School of Medicine

University and Hospital Appointments and Committees:

Professor of Clinical Pediatrics, St. Louis Children's Hospital - Division of Allergy
and Pulmonary Medicine, Washington University School of Medicine

Medical Licensure and Hospital Appointments and Committees:

State of Missouri - #R9698 - 8-3-79
7-2-79 - National Board of Medical Examiners #194924
10-17-82 - American Board of Pediatrics #28242
10-3-83 - American Board of Allergy/Immunology #2328

Military Services:

N/A

Honors and Awards:

Academic scholarships awarded 1971, 1972, 1973, and 1974
A.O.A. Outstanding Senior Student of the Class of 1978

CURRICULUM VITAE - Ray S. Davis, M.D.

Professional Societies and Organizations:

Fellow, American Academy of Allergy, Asthma & Immunology
Fellow, American College of Allergy Asthma and Immunology
Missouri State Allergy Society
Southern Medical Association
Joint Council of Allergy & Immunology

Major Invited Professorships and Lectureships:

N/A

Consulting Relationship and Board Memberships:

N/A

Research Support (role, title, duration, amount):

Governmental N/A

Non-Governmental N/A

Clinical Title and Responsibilities:

Professor of Clinical Pediatrics, St. Louis Children's Hospital,
Division of Allergy Immunology and Pulmonary Medicine
Washington University School of Medicine, St. Louis, MO

Teaching Title and Responsibilities:

Same

CURRICULUM VITAE - Ray S. Davis, M.D.

Reviewer for the Annals of Allergy Asthma and Immunology Journal 2006-11.

Reviewer for the Journal of Allergy & Clinical Immunology 2009.

Reviewer for the Allergy & Asthma Proceedings 2008-2011.

Bibliography:

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Davis RS, Larsen G. Use of videography in the diagnosis of exercise-induced vocal cord dysfunction: A case report with video clip. *J Allergy Clin Immunol* 119:1329-31,2007.

Davis RS, Settupane R, et.al . Problem-based learning: Chronic cough—an interactive case discussion. *Allergy Asthma Proceedings* 2006;27;17-20

Davis RS, Vanderwalker ML, Slavin RG, et al. Facial angioedema in children Due to ladybug (*Harmonia axyridis*) contact: 2 case reports. *Ann Allergy Asthma Immunol.* 2006;97:440-442.

Bukstein DA, Gepner A, Luskin A, Davis RS. Proactive education for asthma Patients. *International Review of Asthma (Japanese)* 2006;8(1);48-57.

Ray S. Davis, M.D., Don A. Bukstein, M.D., Allan T. Luskin, M.D., JA Kailin, G.Goodenow, R.N. Changing Physician Prescribing Patterns Through Problem-based Learning: an Interactive Case-based Education Program. *Ann Allergy Asthma Immunol.* 2004;93:237-242.

In Bukstein, D.A., Strunk, R.C., eds. *Manual of Clinical Problems in Allergy Related Disorders.* Little Brown and Company, Boston, 1984. Author of the following chapters:

Outpatient Treatment of Asthma
Urticaria
Antihistamines
Allergic Rhinitis

Davis, R.S., Larsen, G.L., Grunstein, M.M. : Respiratory response to intra esophageal acid infusion in asthmatic children during sleep. *J Allergy Clin Immunol* 72:393, 1983.

CURRICULUM VITAE - Ray S. Davis, M.D.

Davis, R.S., Remigio, L.K., Schochet, A.L., Bock, S.A. : Evaluation of a patient with both aquagenic and cholinergic urticaria. *J Allergy Clin Immunol* 68:479,1981.

Davis, R.S., Strunk, R. : Auriculotemporal syndrome in childhood. *Am J Dis Child* 135:832, 1981.

Cook, L.N., Davis, R.S., Stover, B.H. : Outbreak of amikacin resistant enterobacteria-ceae in an intensive care nursery. *Pediatrics* 65:264, 1980.

Davis, R.S., Stoler, B.S. : Febrile reactions to Isoniazid. *N Engl J Med* 297:337, 1977.

Davis, R.S., Flynn, M.B., Moore, C: An unusual presentation of carcinoma of the lung - 26 cases of cervical lymph node metastases, *J Surg Oncol* 9:503-507, 1977.

Stoler, B.S., Davis, R.S.: Corticosteroids in postinfluenzal respiratory distress syndrome. *J Kentucky Med Assoc* 75:367-371, 1977.

CURRICULUM VITAE - Ray S. Davis, M.D.**Presentations:**

I have been asked to create a 4 hour workshop to train allergists in PBL facilitation skills chosen from each Committee of the AAAAI at the upcoming annual meeting in Orlando in March 2011. The AAAAI executives want more PBL talks to be done at annual meetings.

I was the speaker/facilitator at a luncheon workshop for the AAAAI Annual Meeting in Miami, FL in March 2006. I taught a workshop on how to become a skilled facilitator of PBL (Problem-based learning) to a small group of allergists.

Davis, R.S., Larsen, G.L., Grunstein, M.M.: Esophageal acid infusion during sleep in asthmatic children with gastroesophageal reflux. Presented to the Pediatric Section, American Thoracic Society's Annual Meeting, Los Angeles, CA, May 17, 1982.

Andrews, B.F., Davis, R.S.: Decreasing Mortality and morbidity in infants of diabetic mothers (presented to the XV International Congress of Pediatrics, New Delhi, India, on October 25, 1977, by B.F. Andrews, M.D., Chairman, Department of Pediatrics, University of Louisville School of Medicine).

Abstracts:

Davis, R.S., et al.: Esophageal acid infusion during sleep in asthmatic children with gastroesophageal reflux. *Am Rev Resp Dis* 125:190, 1982.

Davis, R.S., et al.: An unusual presentation of carcinoma of the lung. *JAMA* 239:662, 1978.

Andrews, B.F., Davis, R.S.: Decreasing mortality and morbidity in infants of diabetic mothers. *Ped Res* 12 (4) : 518, 1978.

CURRICULUM VITAE - Ray S. Davis, M.D.**SPEAKER'S BUREAUS:**

For the past 20 years I have been on the Speaker's Bureau for various pharmaceutical companies including Merck, Genentech, Novartis, Glaxo Smith Kline, MEDA, Alcon, Dey & AstraZeneca. I have led over fifty conferences per year (some were for CME) on allergies, asthma and food allergies & anaphylaxis for the past fifteen years. They have virtually ALL been by **PROBLEM-BASED LEARNING (PBL)**, also known as interactive case discussions. Most of these conferences have been in small groups of between five to fifteen participants. Most have been comprised of primary care physicians (pediatricians, internists and family physicians), nurse practitioners, physician assistants, nurses, pharmacists or pharmacy doctoral students and even specialist groups of allergists and pulmonologists. Moreover, I have been in charge of setting up the PBL faculty and cases to be presented in several national conferences in the last few years mainly involving specialists.

Teaching other specialists to become skilled facilitators in Problem-based learning:

I have trained over 300 specialists in how to become ***"skilled facilitators"*** of Problem-based learning (PBL) workshops/seminars. Some were done for Pharmaceutical companies' speaker bureaus for promotional talks and others were done for CME projects for both live face to face meetings and on web conferences. Specialists who have been taught to become skilled PBL facilitators include 1) allergists and pulmonologists for asthma and rhinitis cases, 2) pulmonologists for COPD cases, 3) cardiologists for chest pain cases, 4) psychiatrists for major depression and bipolar disease cases, 5) neurologists and rheumatologists for fibromyalgia cases and 6) an orthodontist for cases requiring braces.

Utilized my copyrighted workbook in Oct./Nov. 2009 to teach 7 faculty members from the Vanderbilt University School of Medicine Cardiology Division to become skilled facilitators of PBL so that they could utilize this format in their annual CME meeting as well as their weekly conferences.

I have taught 5 groups of 12 (60) psychiatrists to become skilled PBL facilitators in 3 all days PBL training sessions for Astrazeneca Pharmaceuticals in 2009.

I was the speaker/facilitator at a luncheon workshop for the AAAAI Annual Meeting in Miami, FL in March 2006. I taught a workshop on how to become a skilled facilitator of PBL to a group of allergists.

Utilized my copyrighted workbook in Dec. 2005 to teach 10 internist/cardiologists how to become skilled PBL facilitators in a 5 hr CME course in Madison, WI, funded by a \$30,000 grant from Astrazeneca pharmaceuticals. The group will be giving PBL talks on hypercholesterolemia all over Wisconsin in 2006.

CURRICULUM VITAE - Ray S. Davis, M.D.

Utilized my copyrighted workbook in June 2005 to teach 10 internist/pulmonologists how to become skilled PBL facilitators in a 5 hr CME course in Madison, WI, funded by a \$30,000 grant from sanofi-aventis pharmaceuticals. The group is doing PBL talks on COPD and acute exacerbations of chronic bronchitis all over Wisconsin.

Several talks and CME presentations of note include:

American College of Allergy Asthma and Immunology, Boston, MA. Nov. 5-7, 2011. I presented a PBL case in a workshop on how and when to step down an asthma patient who is taking an ICS/LABA medication followed by a lecture on this subject by Len Bacharier on the evidence based literature on this subject.

Eastern Allergy Conference, W. Palm Beach, FL, June 1-3, 2011. I was asked to integrate two separate PBL cases for each of two days. The cases were focused on 1) How and when to step down an asthma patient who is taking an ICS/LABA medication and 2) A patient with chronic rhinitis, sinusitis and otitis who ultimately had COVID. Each case was interactively discussed in small breakout sessions and then follow up didactic lectures "in context" based upon the case Objectives were given in the large lecture room.

North American Rhinology and Allergy Conference, Puerto Rico, Feb.3-6, 2011. I was asked to integrate a challenging PBL case of an adult with chronic rhinosinusitis, nasal polyps and subtle aspirin sensitivity into the first ever combined meeting of otolaryngologists and allergists. The PBL case was interactively discussed in each of the small breakout sessions with follow-up didactic lectures given immediately afterwards "in context" to the case based upon each case's objectives. These post PBL lectures were given to the entire group of attendees reassembled in the lecture hall.

Intermountain West Allergy Association conference, Park City, Utah, July 15-18, 2010. I was asked to integrate two separate PBL cases for each of two days. The cases were focused on 1) Chronic urticaria and 2) Anaphylaxis. Each one hour breakout session was interactively discussed in small sessions with follow-up didactic lectures given immediately afterwards "in context" to the respective cases based upon each case's objectives. These post PBL lectures were given to the entire group of attendees reassembled in the lecture hall.

American Academy of Allergy Asthma and Immunology Annual Conference, New Orleans, LA, February 2010, I did one 2 hour workshop to integrate PBL into their curriculum. The subject was "Stinging Insect Anaphylaxis." After I did a case of a patient with anaphylaxis from an insect sting, Mark Dykewicz, MD did the mini-lecture on the Practice Parameters on the same subject to solidify the key teaching points

CURRICULUM VITAE - Ray S. Davis, M.D.

Eastern Allergy Conference, W. Palm Beach, FL, May 6-9, 2010. I was asked to integrate two separate PBL cases for each of two days. The cases were focused on 1) Food allergy & anaphylaxis and 2) Allergic rhinitis. Each case was interactively discussed in small breakout sessions and then follow up didactic lectures “in context” based upon the case Objectives were given in the large lecture room.

Intermountain West Allergy Association conference, Sun Valley, Idaho, July 16-18, 2009. I was asked to integrate two separate PBL cases for the first time ever into this conference on two separate days into their previously traditional non-stop lecture format. The subjects of the PBL cases were stinging insect anaphylaxis the first day and a child with poorly controlled asthma on inhaled corticosteroids the second day. Three breakout groups debated the cases, then after the breakout groups re-convened in the lecture hall, an expert on each subject delivered a lecture “in context” about the patient discussed referring to established guidelines.

Eastern Allergy Conference, W. Palm Beach, FL, April 30-May 3, 2009. I was asked to create and integrate a PBL case of an adult with poorly controlled asthma who ultimately turned out to have Churg Strauss Syndrome. As we always do, four breakout sessions interactively debated diagnosis and therapy for this patient and then we coordinated a series of three mini-lectures to reinforce the proper differential diagnosis and therapy by evidence-based medicine.

Southwest Allergy Forum, Puerto Vallarta, Mexico, January 14-18, 2009. I was asked again to create and integrate a PBL case regarding “an adult with severe persistent asthma” vs. COPD. Four breakout sessions interactively debated diagnosis and therapy for this patient and then we coordinated a series of three mini-lectures to reinforce the choices for therapy by evidence-based medicine.

American College of Allergy Asthma and Immunology Annual Conference, Seattle, WA November 2009, I did two 2 hour workshops to integrate PBL into their curriculum for the first time. The first workshop was on the subject of “Stinging Insect Anaphylaxis.” After I did a case of a patient with anaphylaxis from an insect sting, Mark Dykewicz, MD did the mini-lecture on the Practice Parameters on the same subject to solidify the key teaching points. The next day, I facilitated a case of a child with poorly controlled asthma who was on inhaled steroid monotherapy and the need for additional second line therapy options were debated. Dr Don Bukstein did the mini-lecture after the case to reinforce the key points from the NAEPP guidelines.

Medical Media Communications asked me to facilitate some more PBL webcons in June and July 2008 for CME on the subject of Restless Leg Syndrome (RLS). I did do so with a “content expert” on RLS online simultaneously who did a followup mini-lecture after the PBL.

Medical Media Communications asked me to facilitate three PBL Web teleconferences for CME credit for allergists and pulmonologists all over the country on the subject of “Severity, Control or Symptoms-Treatment Guidelines and Optimal

CURRICULUM VITAE - Ray S. Davis, M.D.

Patient Outcomes.” I was asked to create the PBL case for myself and other facilitators to utilize. These PBL webcons aired live in February 2008.

Eastern Allergy Conference, Naples, FL, May 1-4, 2008. I was asked to integrate another PBL case into the curriculum. This case was a pediatric asthma patient who was poorly controlled on inhaled corticosteroids alone. This led to a heated discussion among the 5 break out groups as to what “add on therapy” would be ideal. After the interactive discussions, everyone came back together into the main lecture hall for a point counterpoint of 3 brief mini-lectures on the three most likely choices for therapy. Then, everyone voted.

Southwest Allergy Forum, Puerto Vallarta, Mexico, January 16-20, 2008. I was asked again to create and integrate a PBL case regarding “step down therapy choices for an adult with mild persistent asthma.” Four breakout sessions interactively debated therapy for this patient and then we coordinated a series of three mini-lectures to reinforce the choices for therapy by evidence-based medicine. Following the lectures there was a brief point counterpoint panel discussion and then the attendees had to commit by voting for one of the choices for therapy for this patient. We will be submitting this experience along with the PBL case for journal publication.

New England Society of Allergy Annual Spring meeting, outside Boston, April 2007. I integrated a PBL case on COPD into the usual lecture curriculum for the first time in their 51 year history of lecture format.

Eastern Allergy Conference at the Breakers Hotel in W. Palm Beach, FL May 10-13, 2007. I once again was in charge of integrating a PBL case into the curriculum for 4 breakout groups. The subject was “What constitutes asthma control,” which was then followed by lectures on the New NAEPP proposed guidelines and lectures on “Control, risk and impairment in asthma.”

Southwest Allergy Forum, Puerto Vallarta, Mexico January 17-21, 2007. I was asked again to integrate PBL into the curriculum. I wrote a case on food allergy and anaphylaxis which was interactively discussed by 5 breakout groups.

Asthma PBL CME Series of Live Meetings & Audio-conferences Spring 2007—I was chairman of this national program for the Med Learning Group and the Postgraduate Institute of Medicine. We trained the 10 PBL speakers in facilitation skills and authored the cases used all over the US.

Eastern Allergy Conference at the Naples Resort & Spa May 4-7, 2006. The conference focused the beginning of each day on a PBL case followed by the small groups reconvening into the large lecture hall for a didactic lecture to reinforce the principles discussed in the PBL cases. The first day the topic was anaphylaxis and the second day was the long-acting beta agonist (LABA) controversy.

CURRICULUM VITAE - Ray S. Davis, M.D.

Southwest Allergy Forum/Combined Annual Meeting of the Eastern Allergy Conference and the Texas Allergy Society in Puerto Villarta, Mexico January 11-16, 2006. I was in charge of the faculty development and implementation of incorporating a PBL case into the curriculum for the first time in the conference's 60 plus years of pure lecture format.

Eastern Allergy Conference at the Breakers Hotel May 5-8, 2005. I was moderator and in charge of faculty development and implementation of incorporating a PBL case into the curriculum for the first time in the conference's 18 years of a pure lecture format.

Worked with a CME organization, Summit Institute of Knowledge, to develop a CME program to include PBL for a case to teach primary care physicians better diagnosis and management of childhood asthma. I did talks for them in New York City, Chicago, Houston & Philadelphia by PBL in the fall of 2005 underwritten by Sanofi-aventis and Altana

Jacksonville Allergy Society Meeting, Feb. 2005, Jacksonville, FL

Missouri Academy of Family Physicians 55th Annual Scientific Assembly, Tan Tara Resort, Osage Beach, MO, June 20, 2003; one adult and one pediatric problem-based learning workshop.

AstraZeneca Faculty Update, Aug. 2003, Ashville, NC.- Moderator of the conference and also presented a PBL case.

AstraZeneca Faculty Update, Aug. 2003, Little Rock, AR

AstraZeneca Faculty Update, Feb.2003, Kansas City, MO

Arkansas Allergy Society Meeting, Jan. 28, 2003, Little Rock, Ark

28th Annual Capital Region's Healthy Review-Primary Care Seminar, Oct. 2-5, 2002. Did two PBL cases in breakout seminars—one adult and one pediatric asthma case.

2002 AstraZeneca Regional Respiratory Faculty Update, Destin, FL, Sep. 27-29, 2002. I did a talk entitled "Should medical talks be more interactive?"

Florida Asthma Allergy & Immunology Society Annual Meeting, June7-10, 2002, Ocean Reef Resort in Key Largo. I did 4 PBL seminars for 60 allergists.

Cape Girardeau Medical Society Annual Allergy Seminar, April 13, 2002

Merck 2001 Arthritis, Analgesia and Respiratory Managed Care Consultants Meeting, San Diego, CA, Dec. 2001(In charge of PBL cases and faculty for

CURRICULUM VITAE - Ray S. Davis, M.D.

interactive discussions for Medical Directors of Managed Care Organizations and Pharm.D.s)

Pediatric Asthma Management Conference, "Tis the Season to be wheezing."
Washington University and St.Louis Children's Hospital, Oct. 2001

Merck Pediatric National Consultants Meeting , San Diego(6/01)—in charge of the PBL faculty & cases for 130 pediatric allergists and pulmonologists.

Missouri School Nurses Survival Training Course (8/01) at Washington University Medical Center, Neuman Education Center

Missouri Assoc. of School Nurses Meeting (4/01), Marriott Hotel, St. Louis

Merck Regional Consultants Meetings, Hilton Head Island & Detroit (4/01 &6/01)
In charge of the PBL faculty & cases

Asthma & Leukotrienes, Washington University Medical School Update(2/10/01)

Merck National Slide Consultants Meeting, Phoenix, AZ, Dec.1-3,2000. Head of PBL faculty where PBL was incorporated into Speakers' Training Meeting

Clinical Allergy for the Practicing Physician
Washington University Allergy & Immunology Update
July, 1998

Aventis Regional Consultants (Specialists) Meeting, Lake of the Ozarks, July, 2000

Medicine Shoppe Pharmacies Regional Conferences in Washington DC
and St. Louis, 1999

Medicine Shoppe International – International Meeting, St.Louis, May, 2000

St. Louis School Nurses Association Meeting at Washington University Conference Center, August, 2000

Abbott Pharmaceuticals National Sales Meeting, February, 2000, Phoenix
Arizona(to train pharmaceutical reps by PBL cases)

St. Louis Pediatric Nurse Practitioners (monthly CME meeting) 1994, 1996,
1998,2004

CURRICULUM VITAE - Ray S. Davis, M.D.

Family Practice & Pediatric Residents and Fellows Conferences for:

St. Lukes Hospital Community Pediatric CME conference by PBL case 7/08.

Children's Mercy Hospital, Kansas City, MO-Allergy Division Conference, April 2005 & Webcam teleconference 2008 PBL cases.

Cincinnati Children's Hospital Pediatric Residents Dinner Meeting, July 2004

Texas Children's Hospital, Combined Allergy and Pulmonary Conference, Houston 6/04

Vanderbilt University, Noon Allergy Conference, Nashville, 4/04

Children's Mercy Hospital, Kansas City, MO, Mar. 2004 and Sept. 2003

Children's Hospital of Wisconsin, Noon Allergy Conference, Milwaukee 7/03,6/05

St.Louis Childrens Hospital Allergy Conferences 1982-2005

Southern Illinois University Medical Center Noon Conference, 1998, Carbondale, IL

St. John's Mercy Medical Center, yearly PBL seminar 1997-2011

Missouri Family Practice Spring Conference, 1999

Deaconess Hospital, Family Practice Dept., 1999

Des Peres Hospital, Family Practice Dept., 1999-2011

St. John's Hospital, Springfield, IL, Dept. of Pediatrics, 1999

Internal Medicine Residents Conferences:

Internal Medicine Residents Noon conferences at St. Lukes Hospital Yearly 2000-2007.

Internal Medicine Residents Conference from Washington University/ Barnes Hospital, 1999, 2003

Internal Medicine Residents Conference from St. John's Mercy Medical Center, 1998

Internal Medicine Residents, St. Mary's Hosp., Clayton, Mo, Mar. & Nov. 2001

CURRICULUM VITAE - Ray S. Davis, M.D.

Managed Care Talks:

Healthcare USA case managers 2003
Blue Cross/Blue Shield, 1998
United Health Care of the Midwest, 1998
Healthcare USA (six talks in 1999), Apr.2002
Cigna Nurse Case Managers Aug. 2002

Other talks outside of St. Louis (talks to community based physicians) :

Oklahoma City, OK July 2008
Dothan, AL & Destin, FL June 2008
Naples & Ft. Meyers, FL Apr. 2008
Salt Lake City, UT Apr 2008
Milwaukee and Madison, WI 2007
Chicago, IL and NY City Nov. 2007
Dallas and Ft. Worth, TX Nov. 2007
Springfield, MO Aug 2007
Tallahassee, Jacksonville, Lake City, Gainesville, Tampa
and Orlando, FL 2/07
Ft. Wayne, IN, June 2007
San Antonio, TX, March 2005
Tampa, FL, Feb. 2005
Cincinnati, OH, July 2004
Indianapolis, Bloomington & Shelbyville, IN, May 2004
Springfield, MO and Joplin, MO, Oct. 2003

CURRICULUM VITAE - Ray S. Davis, M.D.

Kansas City, MO and Lawrence, KS, Sept. 2003, April 2004, Oct.2004

Madison, WI, July 2003

Louisville, KY, May 2003, April 2005, June 2007

Miami & W.Palm Beach, FL, Feb.2003

Little Rock, AK, Jan.2003

Orlando, FL, Oct. 2002, Nov.2004

Daytona, FL, Oct. 2002

Jacksonville, FL, Oct. 2002, Feb.2003, Nov.2004, Feb.2005

Ft.Lauderdale, FL, June 2002

Denver and Boulder, CO, Mar. 2002, Mar.2003

Madison, WI, Oct. 2001

Phoenix, AZ, Aug. 2001, Jan.2002

Tucson, AZ, Aug. 2001, Jan. 2002

Nashville, TN, July 2001, Oct.2003

Chatinooga, TN, July 2001

San Diego, CA, June 2001

Santa Fe and Albuquerque, NM, Mar. 2001

Ft. Lauderdale, FL, June, 1998, June, 1999

Dallas TX, September, 2000

Bloomington, IN, October, 2000

Alton & Belleville, IL, 1998

Farmington, MO, 1999

Festus, Crystal City, MO, 1999, 2004,2006

CURRICULUM VITAE - Ray S. Davis, M.D.

Evansville and Jasper, IN, Feb. 2001

Columbia and Jefferson City, MO, Feb. 2001,2002, May 2004

St. John's Hospital Staff Noon Conference, 1998, Washington, MO

Cape Girardeau, MO, 1999

Fairfield, IL and Centralia, IL, 2002

Washington, MO, 2002, 2004

Hopkinsville and Paducah, KY, Oct. 2003

Additional Nurses Talks:

St. Louis Area Pediatric Nurse Practitioners, Oct. 2004

Southern Illinois Univ. Nurse Practitioners, Feb. 2001, Feb. 2002, Feb.2003,
Nov.2004

Parkway School District Nurses Meeting, 2000, Jan. 2007

Hazelwood School District Nurses Meeting, 2000

Ft. Zumwalt School District Nurses Meeting 2001

EXHIBIT 23

Expert Report from Phil Lieberman, MD

INTRODUCTION

My name is Phil Lieberman, M.D. I have been asked to provide an expert witness report on behalf of Mylan, Inc. in regards to the Epi-Key versus EpiPen trademark dispute. I was asked to comment on whether the term "EpiPen" has become the generic term for epinephrine auto-injectors, and to comment on the relationship of the term "epi" to the drug epinephrine.

QUALIFICATIONS

I feel qualified to comment in both of these areas since I have over 40 years of experience as an allergist/immunologist, and have published extensively in the area of anaphylaxis, with special reference to the use of epinephrine as therapy for anaphylaxis events, and the employment of epinephrine auto-injectors specifically as treatment of these events in patients experiencing anaphylactic episodes away from medical facilities. I have personally treated numerous cases of anaphylaxis and have written hundreds of prescriptions for automatic epinephrine injectors.

I am a Past President of both the American Academy of Allergy, Asthma, and Immunology and the American Association of Certified Allergists. I have served on the Board of American Academy of Allergy, Asthma, and Immunology.

My first publication dealing with anaphylaxis appeared in the early 1980s, and my most recent was published in 2010 and served as the guidelines that allergists/immunologists use to prevent and manage anaphylactic episodes. These can be seen in my Curriculum Vitae under the section "Book Chapters, Books and Reviews," listed as References 12 and 220, respectively. I have written specifically about the use of epinephrine with emphasis on its outpatient administration as well, as seen in Reference 148 of my CV.

I graduated from Tulane University and then attended medical school at the University of Tennessee, College of Medicine in Memphis. I completed a residency in the field of Internal Medicine at this university, and then an Allergy/Immunology Fellowship at Northwestern University Medical School in Chicago, Illinois.

From there I was appointed as Chief of the Division of Allergy/Immunology at the University of Tennessee, Center for the Health Sciences, a position that I held for 10 years. I then went into private practice where I have remained since that time. I still have a position at the University of Tennessee as a Clinical Professor of both Medicine and Pediatrics in the Divisions of Allergy and Immunology.

I have been a consultant at all hospitals in Memphis, including the University Hospital, Methodist Hospital, Baptist Hospital, and St. Francis Hospital.

I continue as a Fellow of the American Academy of Allergy, Asthma, and Immunology, the American College of Allergy, Asthma, and Immunology, and am a member of the American Thoracic Association.

My Curriculum Vitae is attached to this document. See Exhibit A.

SUMMARY

It is important when considering whether the name of a product has become generic to review the history of the availability of the product in the United States. The EpiPen automatic epinephrine injector was launched in the United States, according to my memory, in the early 1980s. It was not until approximately 2005 when its first competitor, the Twinject automatic epinephrine injector, was launched, and not until approximately four to five years later when its second competitor, the Adrenaclick automatic epinephrine injector, was launched in the United States. The point being that from the early 1980s until 2005 (a period of at least 20 years), the only automatic epinephrine injector on the market in the United States was the EpiPen automatic epinephrine injector.

Prior to that time there was a preloaded epinephrine injector called an "Ana-Kit." However, it did not inject the drug automatically. It was a syringe pre-loaded with epinephrine. The patient injected the drug as a nurse or doctor would any other drug.

When the EpiPen automatic injector became available, because of its ease of use, its sales rapidly outdistanced that of the Ana-Kit, and it became the sole product of its sort on the market, dominating sales, for at least, according to my recollection, two decades.

The next important point regarding whether the EpiPen epinephrine auto-injector has become genericized involves the understanding of how drugs are referred to. Each drug belongs to a class. In my view, the EpiPen belongs to a class of drugs known as automatic epinephrine injectors. All drugs used in the United States fit this prototype. The best analogous example of this is another drug which allergists/immunologists use on a daily basis, albuterol. Albuterol, like epinephrine, is delivered via a device. For albuterol, the device is called a metered-dose inhaler. There are three branded metered-dose inhalers available on the market at the present time. These are ProAir metered-dose inhaler, Proventil metered-dose inhaler, and Ventolin metered-dose inhaler. Quite clearly, when patients and physicians refer to these drugs, they do not refer to them as "ProAir metered-dose inhaler", "Proventil metered-dose inhaler", or "Ventolin metered-dose inhaler". They refer to them simply as ProAir, Proventil, and Ventolin.

But more important is the history underlying albuterol delivered as a metered-dose inhaler and how this history has affected the terminology. Ventolin and Proventil were originally available as metered-dose inhalers powered by chlorofluorocarbons. When chlorofluorocarbons were banned, it became necessary to find a substitute, which was hydrofluoroalkanes. For a period of time, no hydrofluoroalkane metered-dose inhaler delivering the drug albuterol was available in a branded form. All available inhalers were at that time generic. When prescribed during that period, the metered-dose inhalers were referred to as albuterol metered-dose inhalers, and both physicians and patients simply used the term "albuterol" to refer to the HFA-powered albuterol

prescriptions. Later, branded drugs became available again, and the drugs once again were referred to by trade names, ProAir, Proventil, and Ventolin.

The essential point is that one would expect a physician or a patient to refer to their EpiPen only by trade name, as they do their ProAir, Ventolin, or Proventil, rather than by the name "EpiPen automatic epinephrine injector." The fact that, over the years while this drug was the only drug on the market, EpiPen was used to refer to the product, has no bearing whatsoever on whether the name has become genericized. It is simply the paradigm that we use, both physicians and patients, to refer to the drugs that are employed for patient therapy in the United States.

I have prescribed all available forms of automatic epinephrine injectors except for a generic brand. Thus, I have written prescriptions for EpiPen automatic epinephrine injector, Twinject automatic epinephrine injector, and Adrenaclick automatic epinephrine injector. I have, however, never prescribed a generic automatic epinephrine injector. The reason is that it puts the patient at risk because it would allow the pharmacist to make a choice as to the injector given to the patient.

What should be clearly understood is that these injectors, although containing the same drug, are not equivalent. The reason for this non-equivalency is that there are differences in the techniques employed to administer each agent. Therefore, the prescription that a patient receives must be for the automatic epinephrine injector they were trained to use in-office. Through a number of studies it has become abundantly clear that training in the use of an automatic epinephrine injector is absolutely essential. Mistakes are made without such training. In addition, it should be noted that oftentimes there may be months between the training that a patient receives in the physician's office, and the time that the injector is administered to treat an anaphylactic event.

If a patient receives an injector that was not used in training, there is a very high likelihood that they will become confused because of differences in administration techniques between the injectors and therefore make a potentially fatal error at the time of administration. This was clearly recognized by the American Academy of Allergy, Asthma, and Immunology and the American College of Allergy, Asthma, and Immunology, and these organizations issued a position statement in 2010 informing physicians of the necessity to assure that generic automatic epinephrine injectors not be prescribed. See Exhibit B.

In addition to the warning to physicians, a patient instruction sheet entitled "Be Aware of Epinephrine Auto-Injector Substitution" was also issued by these organizations. See Exhibit C. Both of these statements, as noted, were approved by the national organizations which set the standards of practice for Allergy/Immunology, and both were issued because of the fear that a patient would receive, if an automatic epinephrine injector were prescribed generically, a device upon which they were not trained. Both cite the dangers of this occurring.

Furthermore, a practicing allergist sent a letter to the American College of Allergy, expressing concern over the potential danger related to prescribing a generic epinephrine auto-injector. See Exhibit D.

Obviously, these statements also highlight the possible dangers involved if two branded preparations, each using different injector techniques, were confused because they had similar names (e.g., both contained "epi"). It is common FDA policy to prevent drugs with similar names from being marketed.

For these obvious reasons, I have never employed the term "EpiPen" to describe any other automatic epinephrine injector, nor have I used the term "Twinject" or "Adrenaclick" in this fashion. To do so would, as noted above, be incorrect since there are distinct and important differences in the use of each of these injectors. In addition, I have never heard any patient refer to the use of their particular injector by any other name, and specifically, I have never heard a patient prescribed a Twinject or an Adrenaclick refer to their device as an EpiPen. I have never heard a physician refer to a Twinject or an Adrenaclick as an EpiPen.

In keeping with this concept, the three letter appellation "epi" should not be used to refer to epinephrine in general, and I have never used this appellation nor heard a physician use it in discussing the outpatient administration of an automatic epinephrine injector. For safety reasons, the use of any abbreviation for any medication is strongly discouraged. In the review course for recertification in Allergy and Immunology, there is an online course which condemns any such abbreviation for a drug of any class.

The distinction between automatic epinephrine injectors becomes further clarified when one looks at the practice of the manufacturers of each brand. I have never heard any of the manufacturers or their representatives refer to their particular drug (e.g., Twinject and Adrenaclick) as an "EpiPen". In fact, they discourage this because, from their perspective, their brand has advantages that are related to the delivery device, and these are emphasized by the manufacturers. No manufacturer has considered their branded drug to be "another EpiPen." And, as noted above, all physicians refer to each individual brand by their trade name and not as an "EpiPen."

CONCLUSION

For the reasons noted above, the brand name "EpiPen" has not become genericized. Although patients, for two decades, referred to their automatic epinephrine injectors as EpiPens, they did so only because this is the way patients refer to all of their drugs; that is, by name. Since this was the only branded name available, it would be unreasonable to expect any other terminology to be used. For example, as noted, patients refer to their albuterol metered-dose inhaler as their Ventolin, their Proventil, or their ProAir; not for example, as their "Ventolin albuterol metered-dose inhaler."

In fact, to refer to an EpiPen as a genericized term would not only be contra to common terminology used in medicine by patients and physicians, but it would be potentially dangerous. This is because although the drug contained in all epinephrine auto injector devices is the same, the delivery systems are different and employ different techniques. The statements by our national organizations issued to both physicians and patients are strong corroboration of the potential danger of genericization.

To consider the term "epi" as referring to epinephrine in general is also strongly discouraged for safety reasons, as noted above. This is true not only for this particular drug but for all drugs. Any course on drug safety for physicians strongly encourages all drugs to be written by their full name, and condemns any use of abbreviations. That practice could also lead to confusion in pharmacies should the term "epi" be used to refer to all epinephrine auto-injectors.

The FDA clearly has regulations that prohibit similar names for different drugs, and as stated, I personally have never heard either a patient or a physician refer to any branded automatic epinephrine injector other than an EpiPen injector by using the term "EpiPen." The manufacturers of each brand clearly discourage this because of the perceived advantages of their devices.



Phil Lieberman, M.D.
Clinical Professor of Medicine and Pediatrics
Division of Allergy and Immunology, Departments of
Medicine and Pediatrics
University of Tennessee, Memphis

EXHIBIT A

Revised 08/05/2011

CURRICULUM VITAE

Name: Phil Lieberman, M. D.

Birth Date and Place: March 20, 1940
Memphis, Tennessee

Marital Status: Married
Three Children

Office Address: 7205 Wolf River Boulevard, Suite 200
Germantown, TN 38138
Phone: (901) 757-6100 – Fax: (901) 757-6109

Clinical Research Center: 7205 Wolf River Boulevard, Suite 200
Germantown, TN 38138
Phone: (901) 757-6100 – Fax: (901) 757-6110

E-mail : aac@allergymemphis.com

Military Service: Captain, Army Reserves
1965-1971

Education: London School of Economics 1961
Tulane University BA Sociology 1962
University of Tennessee - M.D. 1965

Internship: City of Memphis Hospital
University of Tennessee
Straight Medicine
1965-1966

Residency: Assistant Resident Internal Medicine
City of Memphis Hospital
University of Tennessee
1966-1967

Associate Resident Internal Medicine
City of Memphis Hospital
University of Tennessee
1967-1968

Chief Resident
City of Memphis Hospital
University of Tennessee
1968-1969

Fellowship: Allergy-Immunology
Northwestern University
1969-1971

Faculty Appointments:

Instructor, Internal Medicine
University of Tennessee
1968-1969

Assistant Professor, Chief
Division of Allergy and Immunology
University of Tennessee
1971-1974

Associate Professor, Chief
Division of Allergy and Immunology
University of Tennessee
1974-1979

Professor, Chief
Division of Allergy and Immunology
University of Tennessee
1979-1981

Clinical Professor of Medicine
Division of Allergy and Immunology
University of Tennessee
1981-Present

Chief, Allergy and Clinical Immunology
Baptist Memorial Hospital
Memphis, Tennessee
1981-Present

Clinical Professor of Pediatrics
Department of Pediatrics
University of Tennessee
1986-Present

Certification:

Diplomate American Board of Internal Medicine - 1970
American Board of Allergy, Asthma and Immunology - 1974
Recertifications: 1977, 1980, 1983, 1985, 1999, 2001

Medical License:

Tennessee - MD005630
Mississippi - 12985

Fellow:

American Academy of Allergy	1977
American College of Physicians	1972
American College of Allergists	1973

Professional Societies:

Mid-South Allergy Society
 Memphis, Shelby County, Tennessee Medical Societies
 American Medical Association
 American Academy of Allergy, Asthma and Immunology
 American College of Allergy and Immunology
 Joint Council of Allergy-Immunology
 American Thoracic Society
 American Association of Certified Allergists
 Mississippi State Medical Association

Officerships and Appointed (elected) Board Memberships

Executive Committee, American Academy of Allergy and Immunology	1983-1991
Secretary, American Association of Certified Allergists	1985
Executive Board, Joint Council of Allergy and Immunology	1985-1990
President Elect, American Academy of Allergy and Immunology	1987-1988
President, American Academy of Allergy and Immunology	1988-1989
Second Vice President, American Association of Certified Allergists	1986-1987
Member, Executive Board, Asthma and Allergy Foundation of America	1990-1994
AAAI Representative, Joint Council of Allergy and Immunology	1990
President, American Association of Certified Allergists	1989-1990
Member, American Board of Allergy and Immunology	1991-through 1996
Treasurer, American Board of Allergy and Immunology	1994-1996
University of Tennessee Heritage Society	2000
Board of Directors, American Lung Association of Tennessee, West Tennessee Regional Council	2006
Editorial Board, Journal of Investigational Allergology and Clinical Immunology	2007 - Present

Committees:

American Academy of Allergy, Food Allergy Committee	1976-1978
Graduate Education Committee, American Academy of Allergy	1976-1979
Postgraduate Education Committee, American Academy of Allergy	1977-1980
Patient Participation Committee, University of Tennessee Center for Health Sciences	1979-1980
Committee on Alternative Forms of Therapy, American Academy of Allergy	1980-Present
Chairman, Committee on Anaphylaxis, American College of Allergists	1983-1986
Member, Constitution and By-Laws Committee, American Academy of Allergy and Immunology	1984-1987
Chairman, Constitution and by-Laws Committee, American Academy of Allergy and Immunology	
Co-Chairman, Committee to Other Medical Organizations, Joint Council of Allergy and Immunology	1985
Member, Undergraduate Committee, American Academy of Allergy and Immunology	1985
Member, Nominating Committee, American Academy of Allergy and Immunology	1987
Member, Program Committee, American Academy of Allergy and Immunology	1987
Member, Medical Scientific Council, Asthma and Allergy Foundation of America	1987
Chairman, Nominating Committee, American Academy of Allergy and Immunology	1989
Chairman, Medical Scientific Council, Asthma and Allergy Foundation of America	1990-1992
AAAI Representative, Mothers for Asthmatics	1990
Co-Editor "Asthma Edition - Abstract-A-Card System"	1991-Present
Chairman, Education and Research Trust, American Academy of Allergy and Immunology	1995
Member, National Committee on Asthma Zero Mortality	
Chairman, Nominating Committee, American Academy of Allergy and Immunology	1994
Co-Chairman of Recertification Exams for Allergy Immunology	1995
Committee for preparation of Medical Knowledge Self Assessment IV and V	
Committee on Committees, AAAAI	
Medical Officers Committee of Asthma and Allergy Care	1997
Allergy Action campaign Advisory Board under the auspices of the Asthma and Allergy Foundation of America	1998
ERT Board of Trustees, American Academy of Allergy, Asthma and Immunology	1998-2001
American Academy of Allergy, Asthma, and Immunology Research Advisory Council	1999
Chairman of Education and Research Trust, American Academy of Allergy, Asthma and Immunology	2001
Member, Certification/Recertification Examination Writing Committee for The AAAAI and ACAAI	2004-Present

Committees (continued from page three):

Awards, Memorials and Commemorative Lectureships Committee of the AAAAI	2005
Allergy and Clinical Immunology: Learning Objectives for Medical Students, Prepared by the American Association of Certified Allergists/American College of Allergy, Asthma, and Immunology, Committee Member	2010

Other:

Author, recertification examination American Board of Internal Medicine
Author, position statement for the American Academy of Allergy and Immunology on the use of cytotoxic tests for diagnosis of etiologic agents responsible for human illness
Author, position statement for *in vitro* allergy testing, *in vivo* allergy testing, and anaphylaxis, American Academy of Allergy and Immunology
Who's Who in America, 50th Edition, 1996
Nominated to *Best Doctors in America*, 1989-2010/2011 (has been named to Best Doctors in America every year since its inception (published Woodward/White, Inc.)
Listed in Memphis Magazine "Top Docs" article, 1996, 2006, 2008, 2009
Listed in "Top Doctors in America" (honor received 2003, 2004, 2005)
Outstanding Alumnus, University of Tennessee, College of Medicine, 2000 - (awarded by Alumni Association based on contributions to community, university, and field of medicine)
Outstanding Faculty Award, University of Tennessee, College of Medicine, 2000
Distinguished Clinician Award, American Academy of Allergy, Asthma and Immunology, 2001
Physician's Recognition Award, American Medical Association, January 1, 2002 - January 1, 2005
Distinguished Fellow of the American College of Allergy, Asthma, and Immunology, 2002
Recipient 2006 Carl Arbesman Memorial Lectureship, American Academy of Allergy, Asthma, and Immunology, 2006
Appointed to the NIAID Food Allergy Clinical Guideline Development Expert Panel for establishing guidelines related to food allergy, 2008
Manager of "Ask the Expert" section of the American Academy of Allergy, Asthma, and Immunology website, November 2008 to present
Editor of Literature Reviews for the American Academy of Allergy, Asthma, and Immunology, 2008 to present
Editor and author of monthly World Allergy Organization literature reviews - "Editor's Choice" with Dr. Juan Carlos Ivancevich, 2011

Community Service:

Youth Sports Committee and Coach, Jewish Community Center	1976-1986
Board of Directors, Anshei Sphard Synagogue	1977
Board of Directors, Jewish Community Center	1978
Maimonides Service Award	1992
Appeals Committee, Jewish Federation	
Committee for Endowed Chair of Medicine for Gene Stollerman at University of Tennessee	1996-1997
Volunteer - Church Health Center	
Community Service Award from Church Health Center - given for providing quality healthcare to a traditionally under-served population through volunteer support	March 27, 2001
Finalist, 4th Annual Health Care Heroes Award, Nominated by Memphis Business Journal	2002

ABSTRACTS

1. **Lieberman P**, Petersen V, Ricks J, Patterson R, Chakrin L, and Wardell JR. Effect of Route of Administration and Type of Antigen on Antibody in the Canine Tracheal Pouch. Presented at FASEB, American Association of Immunologists, (ABST) April 1971.
2. **Lieberman P**, Berlin B, and Patterson R. Respiratory Immune Response of Dogs to Influenza Virus. Presented at American Association of Microbiologists, (ABST) May 1971.
3. Patterson J, Harwell WB, **Lieberman P**, and Beachey E. Platelet Aggregation in Atopic and Normal Subjects. Presented at the American Academy of Allergy, (ABST) February 1973. *Journal Allergy and Clinical Immunology*, 49:87, (ABST) 1972.
4. **Lieberman P**, Patterson J, Harwell WB, and Beachey E. Platelet Aggregation in Atopic and Normal Subjects. Presented at Southern Section of APCR, (ABST) January 1973.
5. Metcalfe D, **Lieberman P**, and Robinson H. Urinary Cyclic AMP in Asthmatics. Presented at Southern Section of APCR, (ABST) January 1973.
6. Mallette J, and **Lieberman P**. The Effect of the Establishment of a Fulltime Allergy-Immunology Service on the Care of Asthmatics in a University-City Hospital. Presented at American Academy of Allergy, (ABST) January 1974. *Journal Allergy and Clinical Immunology*, 53:78, (ABST 33) 1974.
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EXHIBIT B

Be Aware of the Generic Epinephrine Autoinjector

Dear Members:

It has come to our attention that there is a generic epinephrine autoinjector (without a specific name) that is being distributed by Greenstone (a generic division of Pfizer). According to Greenstone's website, this injector is identical to a product named *AdrenaClick*, distributed by Shionogi Pharma. Apparently Shionogi has authorized Greenstone to distribute the same device as an unbranded or "generic" item.

We call your attention to this because it may result in substitution by the pharmacy of the generic for a brand name prescription, or vice versa. The issue which merits comment is that the instructions for the administration of *EpiPen*, a product distributed by Mylan Pharmaceuticals, is different than the instructions for the administration of either the *AdrenaClick* or the "generic" automatic epinephrine injector. There is presently no generic autoinjector which employs the same administration technique as the *EpiPen*.

Thus, you may have trained your patient for the administration of one type of injector, and the pharmacy may provide another type on which the patient has not been trained. During the stress of an anaphylactic reaction, this may be confusing to a patient and could result in the delay or perhaps an error in the administration of the drug.

You can view each type of injector and the instructions for its administration at each of the respective websites: www.adrenaclick.com; www.epipen.com; dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=16934

Sincerely,

Mark Ballow, MD, FAAAAI,
FACAAI
President, AAAAAI

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You have received this message because you are a member of the AAAAAI or have had previous contact with the AAAAAI. If you do not wish to be included in our e-mail list, please forward this message to info@aaaai.org.

EXHIBIT C

Be Aware of Epinephrine Autoinjector Substitution

This article has been reviewed by Thanai Pongdee, MD, FAAAAI

An epinephrine autoinjector is used to treat a severe allergic reaction or to prevent anaphylactic shock caused by stinging insects, foods, latex, medications or other allergens.

If you have a severe allergy and carry epinephrine, it is important to know that each brand functions a little differently. The stress of an anaphylactic reaction is not the time to realize you have a different autoinjector than what was demonstrated to you by your allergist.

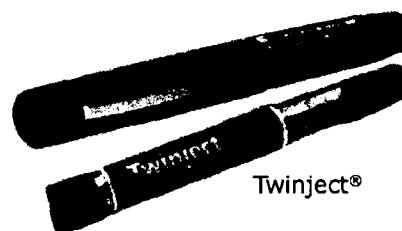
There are three readily available brands of epinephrine autoinjectors: EpiPen®, Adrenaclick® and Twinject®. Adrenaclick is sometimes substituted for EpiPen, depending upon the prescription from your doctor, the pharmacy you use to fill your prescriptions and your insurance coverage. Although the medication is the same, the method for injecting it is a little different in each brand.

The next time you pick up your prescription, be sure to compare the brand you received with the brand you have been trained to use. If the medication appears to be different than what you expected, find out why a substitution was made. Also, be sure to get a demonstration on how to use the product.

Your pharmacist and your doctor's office want to make sure you know how to use the autoinjector in an emergency, so ask as many questions as you need to feel comfortable. If you have additional concerns, contact your allergist for more information.

DID YOU KNOW?

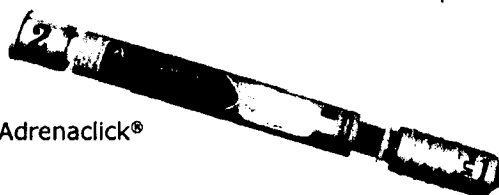
- It is estimated that the number of cases of anaphylaxis in the United States from foods increased from 21,000 per year in 1999 to 51,000 per year in 2008.
 - Food allergies cause approximately 150 to 200 fatalities per year.
 - Fatal food anaphylaxis is most often caused by peanuts (50-62%) and tree nuts (15-30%).
-



Twinject®



EpiPen®



Adrenaclick®



*Your source for more information
or to find an allergist/immunologist.*

To the Point

Be sure to discuss your prescription with your allergist and pharmacist so you know exactly which brand of epinephrine autoinjector you are receiving and how to use it.

EXHIBIT D



Allergy and Immunology
Glossary

Ask the Allergist

Patient's Rights on Health
Care Reform

Letters to the Editor

Patient Newsletter

FAQ

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Patient Support
Organizations

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Top Allergy Content

FOOD ALLERGIES
SKIN ALLERGIES
EYE ALLERGIES
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LATEX ALLERGY
SINUSITIS
RHINITIS

Top Asthma Content

ASTHMA SYMPTOMS
ASTHMA TREATMENT
CHILDHOOD ASTHMA
ASTHMA TRIGGERS
ASTHMA SCREENING

Generic Epinephrine Injector May Cause Confusion

Epinephrine is a cornerstone medication in the treatment of **anaphylaxis**. As allergists we routinely prescribe this medication for many of our patients. For years we only had to remember the name EpiPen (<http://www.epipen.com/>) as it was the sole product available for our patients to safely and easily use. Recently we added new injectors, the latest being the Adrenaclick (<http://www.adrenaclick.com/>).

In May 2010 a "generic" epinephrine auto-injector was released for distribution. This epinephrine auto-injector (<http://dailymed.nlm.nih.gov/dailymed/druginfo.cfm?id=13934>) has no trade name currently (it is distributed by Greenstone, a generic division of Pfizer). It has been authorized by Shionogi, the maker of the Adrenaclick, as a generic of the Adrenaclick. This is somewhat confusing as all of the auto-injectors are considered by the FDA as BX rated indicating that the FDA has determined that there is insufficient data showing that epinephrine auto-injector products are therapeutically equivalent and safe to substitute. Normally to be generically equivalent a drug would have an AB rating.

The EpiPen does not currently have a generic auto-injector and the Greenstone generic epinephrine auto-injector cannot be substituted for the EpiPen.

In an informal survey of patients and pharmacists in Missouri, there is some concern about what products the patients may receive. Patients report they would like to continue to receive the same auto-injector they had previously and are concerned they might not know how to use a new injector if a substitute is given to them without instruction. Pharmacists have yet to see the new auto-injector and most were unaware of its existence. One pharmacist was very concerned that EpiPen prescriptions might get substituted in less scrupulous pharmacies. Other pharmacists freely admit that they do not always take the time to instruct the patients in the use of the auto-injectors. When asked the pharmacists agree that this a formula for confusion and potentially a reason for delay or error in administration of the epinephrine.

Here are a few tips to decrease the confusion. For the prescriber: Write for the exact product that you and the patient agree upon and sign dispense as written on the prescription. Make sure that the patient has been instructed in your office in the use of the specific injector. Empower your patient to check out their epinephrine auto-injector BEFORE they leave the pharmacy.

For the patient: Make sure you know how to use your auto-injector before you leave your doctor's office. Check your auto-injector IN the pharmacy and make sure you are getting the product your doctor prescribed and trained you on. If you determine that a legitimate substitution has been made, make sure you are trained in its use and comfortable with the new injector before leaving the pharmacy. Epinephrine is life saving and you should be able to competently use this for yourself or a loved one.

You can view each type of injector and review the instructions for their administration at the websites listed above.

Janna Tuck, MD, FAAAAI
Allergy Partners of Cape Girardeau
Cape Girardeau, Missouri

ALLERGY AND ASTHMA
SUCCESS STORIES



Read stories of people just like you. Learn how they found relief from their allergy and asthma symptoms by visiting an allergist.

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FIND AN ALLERGIST



Allergists are specialists at treating both allergies and asthma. They can explain how your allergies can affect

your asthma and steps you need to take to keep both conditions under control. Find an allergist in your zip code and find relief.

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Allergies

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Treatment
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Seasonal
Anaphylaxis

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Symptoms
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Top Content

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Eye Allergies
Dust Allergy
Allergy Testing
Pet Allergies
Drug Allergies
Allergic Rhinitis

Other Resources

Find an Allergist
Household Allergies
Seasonal Allergies
Ask the Allergist
Patient Stories
Patient Support
Organizations
ACAAI Research
Letters to Web Editor

About the ACAAI
Members
Fellows in Training
Allied Health
Professionals
Alliance
ACAAI Foundation
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EXHIBIT 24

Expert Report From Martha V. White, M.D.

My name is Martha V. White, M.D., and I've been asked to address the question of whether the term "EpiPen" has become the generic term for "epinephrine auto-injector."

Qualifications

I feel that my training and experience make me well qualified to address this question, as I have been a practicing allergist since 1984, and have been board certified in allergy and immunology since 1985. I graduated from Virginia Commonwealth University School of Medicine in 1978, completed three years of Pediatric training at the same institution, then completed two years of Allergy/Immunology training at the University of Southern California and Georgetown University (one year each). Following my Allergy/Immunology Fellowship, I worked in the Allergic Diseases section of the Laboratory of Clinical Investigation, a laboratory in the National Institute of Allergy and Infectious Diseases at the National Institutes of Health (NIH), where I spent nine years performing research in the field of allergic inflammation and coordinated the pediatric part of the NIH Allergy Fellowship program. During one of those years I was employed by the Food and Drug Administration (FDA), but continued my research at the NIH. After leaving the NIH in 1993, I helped to form the Institute for Asthma and Allergy, where I am a practicing allergist and have served as director of research since we began clinical trials in early 1994. To date, I have been an investigator in over 200 clinical trials in a variety of allergic disorders. I believe strongly in patient education, and as such, am a founding board member of the Allergy and Asthma Network/ Mothers of Asthmatics, a lay organization devoted to patient education and advocacy for allergy and asthma patients and their families. My curriculum vitae is attached to this report as Exhibit A.

Summary:

There are three marketed brands of epinephrine auto-injectors that I am aware of: EpiPen, produced by Mylan, Inc.; Twinject, produced by Shionogi Pharma and Adrenaclick, also produced by Shionogi. Recently, Greenstone has received FDA authorization to market a generic version of the Adrenaclick, also produced by Shionogi Pharma, and identical to the branded version. It is marketed under the name of Epinephrine auto-injector; thus the generic device is not a distinct device. All four products are available in either 0.15 mg or 0.3 mg doses of epinephrine. The Twinject contains two doses in one device, while the others contain a single dose. While all three distinct products contain epinephrine, the mechanics of actual use are quite different, making these products distinct and not interchangeable. Because these devices are meant to be used by non-medical personnel under emergency, often life-threatening circumstances, hands-on patient instruction on the prescribed device is critical to a successful outcome. Thus, when I prescribe an EpiPen, I am referring to the trademarked product produced by Mylan, Inc., and I expect the pharmacist to dispense an EpiPen. To do otherwise would potentially endanger my patient's life. Thus, it is my opinion that the

term EpiPen is a trademarked name of a particular epinephrine auto-injector, not to be confused or substituted with the Twinject, the Adrenaclick, or the generic version of the Adrenaclick.

Discussion:

My patient population includes both adults and children with asthma and a variety of allergic disorders, including food and hymenoptera allergies (i.e., yellow jackets, honey bees, etc.). Allergic reactions to food and hymenoptera include airway obstruction and hypotension leading to shock, and such reactions can be life-threatening. The standard of care for food and hymenoptera allergy includes a prescription for an epinephrine auto-injector which should be available to the patient at all times in the event of anaphylaxis.

I believe strongly in patient education and have personally provided my patients with hands-on education on the use of epinephrine auto-injectors. These products are designed to be life-saving treatments used in emergency situations by non-medical allergy patients or their care-givers. In studies of fatal anaphylaxis from food ingestion, the most common finding is delayed use or failure to use epinephrine after the onset of anaphylaxis. Being both knowledgeable about and comfortable with the mechanics of using the epinephrine auto-injector is critical for a successful outcome.

There are three branded epinephrine auto-injectors that I am aware of: the EpiPen, the Twinject (containing two doses in one device), and the Adrenaclick (a single dose version of the Twinject, now also available in an identical generic version). All three products contain epinephrine and all three are shaped similarly (EpiPen is long and oval, while the other three are long and round). However, as one who has actually handled both the EpiPen and the Twinject products, it is obvious to me that here is where the similarity stops. Just as various makes of automobiles differ in their mechanical properties, the EpiPen differs from the Shionogi Pharma products in its mechanics of usage as described below.

The Twinject is a small cylindrical device containing two doses of epinephrine. To use it requires two hands. One must take the device out of its case, remove caps both at the top and the bottom of the device, then press the correct end at a 90 degree angle into the thigh to trigger a spring loaded injection. The process usually requires that the device be manipulated from one hand to another, and once the injection has been delivered, a contaminated needle remains exposed at the end of the device. In case a second dose is required several minutes later, it is necessary to keep the needle from coming into contact with surfaces in the environment. If the second dose is required, one must unscrew the cap at the base of the exposed needle and carefully lift the cap up and over the needle, taking precautions to avoid accidental needle stick injury. During this procedure a spring sometimes comes flying out of the device. A syringe is then extracted from the device, a safety clip must be removed, and the needle is then injected into the muscle, and the barrel of the syringe manually depressed by the patient or care giver. I have heard that some school nurses refuse to accept the Twinject from their students

because of the risk of accidental needle stick injuries, and also because of a concern that, since the syringe can be accessed by unscrewing the inside cap, students might bring in devices in which the contents have been replaced with illegal drugs.

The Adrenaclick is identical to the Twinject except that it contains only a single dose. Thus, the three-step instructions for use are identical to those of the first dose of the Twinject. After injection, an exposed, contaminated needle remains on the device.

The EpiPen is a long oval device, ergonomically designed to be held in the fist, and can be operated easily with one hand. Thus, a caregiver of a struggling child can hold the child with the non-dominant arm and hand, while operating and administering the EpiPen with the dominant hand. The hard case holding the device can be opened with the flick of the thumb. After removal from the case the device can be grasped in the fist, and the blue safety cap flicked off with an upsweep of the thumb. The device is already in proper position to press the black tip of the device at a 90 degree angle into the thigh muscle to trigger a spring loaded injection. As the device is removed from the leg, a safety sheath springs out and covers the contaminated needle. The syringe is encased within a hard plastic shell, and cannot be accessed.

When prescribing an epinephrine auto-injector, my overwhelming preference is for the EpiPen because of its ease of use. When shown both the Twinject and the EpiPen techniques, I can recall only one patient who stated a preference for the Twinject, even if the EpiPen was more expensive under the patient's insurance plan. This is true even for those who anticipate requiring only a single dose, mainly because of the one-handed design of the EpiPen. Thus, when I prescribe an EpiPen, I am referring to the branded product produced by Mylan, Inc. , and that is the product that my patient will have been trained on. The various epinephrine auto-injectors are not interchangeable, and substitutions are potentially dangerous and could lead to fatal outcomes.

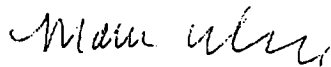
I have read Dr. Amin Mery's report, and I must respectfully, but strongly disagree with him over his statement that "It is my opinion that patients, physicians, and the public in general are using the term "epipen" to refer to any epinephrine auto-injector containing epinephrine. Therefore the trademark EPIPEN has become genericized." I note that he referred several times to having a Twinject, Adrenaclick, or the generic Adrenaclick in the office. I did not find any mention that he had actually used or handled an EpiPen before, and perhaps this may explain why he fails to appreciate the significant differences between the EpiPen and the three Shionogi Pharma devices.

In fact, the differences between an EpiPen and the other three epinephrine auto-injectors on the market are both mechanically and therapeutically significant. Allergic patients require training on the specific devices prescribed, and failure to receive the device on which the patient has had specific training could lead to mechanical failure in life-threatening situations. That patients understand the difference between the devices is evidenced by this passage from the "Hot Topics media Center of the Food Allergy and Anaphylaxis Network website (<http://www.foodallergy.org/page/epinephrine-auto-injectors--patients-may-need-re-training>): "If you or someone you know has been

prescribed an epinephrine auto-injector, please be aware that specific brand-name epinephrine auto-injectors, such as Adrenaclick™, EpiPen® or Twinject™, as well as the generic version, each have their own unique instructions for proper administration." The full webpage on which this statement appears is attached to this report as Exhibit B. The topic has also been addressed by the Allergy and Asthma Network/Mothers of Asthmatics on its web site (<http://www.aanma.org/2010/06/epipens-and-so-called-generic-versions-the-facts/>) as follows: "Recent news reports have presented patients with conflicting and confusing information about EpiPen Auto-Injector and a so-called generic version. These articles contain information that is inaccurate, inflammatory and, in some instances, dangerous." The full webpage on which these statements appear is attached to this report as Exhibit C.

Thus, clearly, the two lay organizations most interested in allergic diseases that might require the use of epinephrine auto-injectors have published statements indicating that there are fundamental differences between the EpiPen and the other epinephrine auto-injectors. I agree with those organizations that the term EpiPen is a trademarked term referring to the EpiPen device made by Mylan Laboratories, and is not a genericized term for epinephrine auto-injectors.

Respectfully,



Martha V. White, MD, CPI

EXHIBIT A

Curriculum Vitae (updated 2-16-2011)

Name: Martha Vetter White, M.D., C.P.I.

Home Address: 4223 Everett Street
Kensington, Maryland 20895
(301)962-6006

Business Address: Institute for Asthma and Allergy, P.C.
11002 Veirs Mill Rd # 414 5454 Wisconsin Ave. #700
Wheaton, MD 20902 Chevy Chase, MD 20815

Phone: 301-962-5800
Fax: 301-962-9585
Email: martywhite@hotmail.com

Date & Place of Birth: October 23, 1951, Richmond, Virginia

Citizenship: United States

Marital Status: Married, two children

Education:

1971 - Vanderbilt University
1973 - B.A., magna cum laude, University of Richmond
1978 - M.D., Medical College of Virginia, Virginia
Commonwealth University

Board Certification:

American Board of Pediatrics, 1983
American Board of Allergy and Immunology, 1985
Certified Physician Investigator (APPI, # FDA-I-0906-064), 2006

Licensure:

Virginia	033800		
District of Columbia	20325	Maryland	D0056193

Brief Chronology of Employment:

1978-1981	Internship and Residency, Pediatrics, Medical College of Virginia, Virginia Commonwealth University, Richmond Virginia
1981-1982	Locum Tenens, Emergency Room, and Public Health Physician, Richmond, Virginia
1982-1983	Fellowship, Allergy and Immunology, University of Southern California, Los Angeles, California
1983-1984	Fellowship, Allergy and Immunology, Georgetown University Hospital, Washington, DC
1984-1985	Guest Worker, Allergic Diseases Section, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland
1985-1986	Staff Fellow, Center for Drugs and Biologics, Allergens Division,

1986-1988	Food and Drug Administration, Bethesda, Maryland NRSA Fellow, Allergic Diseases Section, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland
1988 -1993	Senior Staff Fellow, Allergic Diseases Section, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland
1988 -1993	Coordinator of Pediatric Allergy, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland
1993 - Date	Director of Research, Institute for Asthma and Allergy, P.C. 11002 Veirs Mill Rd # 414 (primary, research & clinical) Wheaton MD 20902 And 5454 Wisconsin Ave #700 (secondary, clinical only) Chevy Chase MD 20815

Societies

Society of Principal Investigators, President (2002-2003)
American Academy of Pediatrics, Fellow
American Academy of Allergy Asthma and Immunology, Fellow
American College of Allergy Asthma and Immunology, Fellow
American Thoracic Society, Member

Honors & Other Special Scientific Recognition:

Beta Beta Beta
Psi Chi
Gamma Sigma Epsilon
Geigy Fellowship, 1984
Asthma & Allergy Foundation of America Fellowship, 1985 (\$5,000)
Norwich Eaton Research Award, 1987 (\$4,000)
Merrell Dow Scholar in Allergy Award, 1989 (\$50,000)
Best Doctors In America
America's Top Pediatricians
Helping Others Breathe Easier Award, 1995 (Allergy & asthma Network/Mothers of Asthmatics)

Special Interests:

Late phase allergic reactions
The role of the mast cell in inflammation
Mast cell physiology
Airway hyperreactivity
Asthma
Sinusitis
Rhinitis

Activities:

Allergy & Asthma Network/Mothers of Asthmatics
Board of Directors, 1987-Present
Medical Editor, MA Report, 1986-Present
Allergy, Asthma & Immunology Guide

Associate Editor, 1989-1990
American Academy of Allergy Asthma & Immunology
Public Education Committee, Member, 1995-present, Co-Chair 1996-7, 2001-2002, Chairman
2002-2004
Post Graduate Education Committee, Member, 1995-1997
Asthma, Rhinitis and Other Respiratory Diseases Interest Section
- Workshops representative 1995-1998
Rhinitis, Sinusitis, Ocular & Dermatologic Interest Section
Secretary 2004-present, Workshops representative 2004-present
- Liason to Charitable Organizations Committee, 1996-present, Chairman, 2002-2004
Allergy & Asthma Network/Mothers of Asthmatics representative
Women's Involvement in the AAAAI Committee, Member, 1998-present
Society of Principal Investigators, Member, 2000-present, Treasurer 2001-2002, President 2002-2003
MKSAP – Allergy & Immunology, Second Edition - Contributor

Research Oversight Activities:

Internal Review Boards: National Institute of Allergy & Infectious Diseases
Member, Clinical Research Committee (IRB), 1990-1992
Medlantic Research Institute
Member, Institutional Review Board, 1996-2001
Member, Research Committee, 1996-2001

Data Safety Monitoring Board: SpineWave 2007- current
Safety Monitoring Committee: Biota 2010- Current (Chair)

Institute for Asthma & Allergy: Research Director: 1993 -current

Industry Interactions:

Clinical Research:

Asthma: 3-M: 1163-BRON, 1192-BRON, 1195-BRON
Abbott: M94-199, M96-464
Astra: 004-3100, 004-0144
Astra-Zeneca: SD-039-0726, SD-004-0764, SD-004-0620, D5896C00005,
D5896C00001, D5896C00022
Aventis: XRP1526B-102, XRP1526B-322, XRP1526B-324, XRP1526B-325,
XRP1526B-342, MO16455P-3001, MO16455P-3003, MO16455A
Boehringer Ingelheim: 205-416
Forrest ADS-401, ANC-MD-03-000, ANC-MD-01-000
Genentech: Q0723G, Q2948G, Q3662G
Glaxo: SFCA3002, SFCA3003, SALA3003, SAS30003, FLTA3020, FLTA4014,
SALA3007, SLGA3009, SLGA5018, NAI30008, SAS40020, SLGA5011,
FMS30058, FMS30059, SAS40024, SAS40025, SAS40026, SFCA3006
GlaxoSmithKline: SAS30022, SAS40036, SFA103153, ADA103578, ADA109055,
HZA113091
Immunex: 13.0014
MedImmune: Medi 563/MI-CP197, CP-198
Merck: MK0467, SNG477/120-01, SNG477/120-05

Miles: HRV Epidemeology Study
Neurobiological Technologies, Inc.: CRF9303, CRF9405
Novartis: RhuMAB-P010, CQAB149-B2338, CQAB149-B2357
Pfeizer: PDEAAS-1500-002
Rhone-Poulenc-Rorer: RG5016Y-204, RG5016T-203, RG5016T-202, RG5016T-303
Sanofi: DFI2588
Scherring: C98-005, PO1431, P04295, P04073, P04334, P04431, P04703
Sepracor: 051-031, 051-202, 110-060, 051-356,
Smith Klein Beecham: 205312/011, 205312/141, 205312/087
Teva : ABS-AS-306
United Biosource Corporation : UBC-A2-6485
Wyeth: PDA-641, 0881A8-205-WW
Zeneca: 9188IL/0150, 9188IL/0139, 9188IL/0060, 9188IL/0079, 9188IL/0156,
9188IL/0155

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Altana: By217/M2-124
Boehringer Ingleheim:, 205-252
Dey: 191-076
Glaxo: SLGA4021, HCZ112207
GlaxoSmithKline: SB207-499-156
Novartis: CNVA 237A-2303
Pfizer: PDEACO-9287-001, A2641022
Sepracor: 051-914, 091-051, 091-061

Allergic Rhinitis:

Alcon: C-00-10, C05-69, SMA-08-06, C-08-32
Altana: BY9010/M1-403
Apotex: Tria-Naso-05RB02-CE
Astra-zeneca: D5360C0073
Aventis: M0164551/3112, MO16455P/2113, M016455C/3212, MO16455A-4120,
M016455A-4143, M016455A-4144, M016455A-4146, M016455M-3002
Curalogic: RPE 04
Dey Laboratories DL-047
Dynavax: DV1-SAR-06
Glaxo: FNM30034
GlaxoSmithKline: FFR106080, FFU111439
Hoechst Marion Roussel, Inc.: M061455/3097, PJPR0009, .M061455/4092, 99-4104
Medeva/Adams: SPX-D9701
MedPointe: 414, 419, 425, 430, 435, 436
Pfizer: L-0325
Scherring: C98-001, P00361, P00677, P01998, P01999, P01875, P01435, P00375,
P02772, P01861, P04095, P05067, P05528, P05233
Sepracor: 110-024, 051-356, 110-073
Strategic Pharmaceuticals: SMAN-0708
Teva: BDP-AR-303

Vasomotor Rhinitis:

Glaxo: FFR 30007
Winston Laboratories: WL-1002-03-01
SRXA: SMAN-0708

Sinusitis: Accentia: ACC-05-01
Bayer: Bay12.8039-100107, Bay D96-024
Medeva/Adams: MEMU-FL1-95-001, MEMU DE20950002, SPX-D9
Scherring: C96-252, C97-251

Urticaria: Hoechst Marion Roussel, Inc.:PJPR0039, M061455/3097, PJPR0009, .M061455/4092,
99-4104
Sepracor: 110-050

Immune Deficiency: Bayer: Bay.100174
Nabi: 7101

Hereditary Angioedema: Dyax: DX-88/4, DX-88/5, DX-88/14, DX-88/19, DX-88/20
Lev Pharmaceuticals: LEVP2005-1, LEVP2006-1, LEVP2006-4, LEVP2006-5
Pharming: C1 12-5-01
ViroPharma: 0624-400
Shire: CB-058

Upper Respiratory Infections: Boehringer Ingelheim: 244-2465

Infectious Diseases: Food Products Assoc: CDC-030

Consulting: Astra
Astra-Zeneca
Aventis
Ciba Geigy
Dey Pharmaceuticals
Dyax
Genentech
GlaxoSmithKline
Hoechst Marion Roussel, Inc.
Lev Pharmaceuticals
MedImmune
MedPointe
Miles
NovoNordisk
Sandoz Pharmarceuticals
SanofiAventis
Sepracor
Zeneca

FDA – Related Consulting:
Dyax
Genentech
Lev Pharma

Novartis

Investment Consulting: Medacorp

Speakers Bureau: Aventis, Inc
Astra-Zeneca
Boehringer
Fisons
GlaxoSmithKelein
Hoechst Marion Roussel, Inc
MedPointe
Merck
Sepracor
ViraPharma
Zeneca

Educational Films: Glaxo Rhone Poulenc Rorer Sepracor
Fisons Hoechst Marion Roussel, Inc. Information Television Network

Television Interviews: All local news stations, MSNBC, Dateline, CNN, since 1993

Expert Witness: Corporate, patent, and medical practice issues since 1995

Medical Malpractice:

Christopher J. Mattingly 1995: plaintiff
Maurice R. Dundie LLP

Amira Archer-Davies v. Raymond Nwadiuko, MD et al. ; 2002 : defendant
Armstrong, Donohue, Ceppos & Vaughan

Berkshire/Atkinson, File No.: 07861.00001; 2004 : plaintiff
Wilson, Elser, Moskowitz & Dicker LLP

Quarles v. Bojan Realty DC File No. 2009CA007111B; 2010: defendant
Hartel, Kane, DeSantis, MacDonald & Howie, LLP

Corporate Patent Law:

Apotex vs Pfizer; 2005 : defendant
Bereskin & Parr, Toronto, Canada

Product Liability:

Various plaintiffs vs McDonald's Corp, 2007 –
Bonner Kiernan Trebach & Crociata LLP

Public Education: MA Report (Allergy & Asthma Network/Mothers of Asthmatics)
Ask Dr. White Column, 1987 – present
Consumer Health Interactive Web page: Ask the Expert