



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Jacob A. Doughty
Oblon Spivak McClelland Maier & Neustadt LLP
1940 Duke St.
Alexandria, VA 22314

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,411,552

MAR 26 2014

Dear Mr. Doughty:

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 5,411,552 for an additional period of 1 year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to any relevant patent expiration dates.

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: SAPIEN
Docket No.: FDA-2012-E-0196

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Edwards Lifesciences AG :
Request for Patent Term Extension : ORDER GRANTING
U.S. Patent No. 5,411,552 : INTERIM EXTENSION

Edwards Lifesciences AG, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 5,411,552, filed an application for patent term extension under 35 U.S.C. § 156 on December 22, 2011. The extended term of the patent is due to expire on May 2, 2014. The patent claims the medical device product SAPIEN Transcatheter Heart Valve which was approved by the Food and Drug Administration for commercial marketing or use on November 2, 2011. An extension of 1,757 days is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the extended term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 5,411,552 is granted for a period of one year from the extended expiration date of the patent.

March 19, 2014

Date



Michelle K. Lee
Deputy Under Secretary of Commerce for Intellectual
Property and Deputy Director of the United States Patent
and Trademark Office



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Jacob A. Doughty
Oblon Spivak McClelland Maier & Neustadt LLP
1940 Duke St.
Alexandria, VA 22314

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,411,552

MAILED
04 29 13
OPLA

Dear Mr. Doughty:

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 5,411,552 for a period of 1 year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates.

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: SAPIEN
Docket No.: FDA-2012-E-0196

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Edwards Lifesciences AG :
Request for Patent Term Extension : ORDER GRANTING
U.S. Patent No. 5,411,552 : INTERIM EXTENSION

Edwards Lifesciences AG, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 5,411,552, filed an application for patent term extension under 35 U.S.C. § 156 on December 22, 2011. The extended term of the patent is due to expire on May 2, 2013. The patent claims the medical device product SAPIEN Transcatheter Heart Valve which was approved by the Food and Drug Administration for commercial marketing or use on November 2, 2011. An extension of 1,757 days is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the extended term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 5,411,552 is granted for a period of one year from the extended expiration date of the patent.

April 1, 2013

Date



Teresa Stanek Rea
Acting Under Secretary of Commerce for Intellectual
Property and Acting Director of the United States Patent
and Trademark Office



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

APR 17 2012

Jacob A. Doughty
Oblon Spivak McClelland Maier & Neustadt LLP
1940 Duke St.
Alexandria, VA 22314

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,411,552

Dear Mr. Doughty:

An order granting interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 5,411,552 for a period of 1 year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to patent expiration dates.

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: SAPIEN
Docket No.: FDA-2012-E-

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Edwards Lifesciences AG :
Request for Patent Term Extension : ORDER GRANTING
U.S. Patent No. 5,411,552 : INTERIM EXTENSION

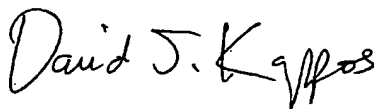
Edwards Lifesciences AG, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 5,411,552, filed an application for patent term extension under 35 U.S.C. § 156 on December 22, 2011. The original term of the patent is due to expire on May 2, 2012. The patent claims the medical device, SAPIEN, which was approved by the Food and Drug Administration for commercial marketing or use on November 2, 2011. An extension of 1,757 days is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 5,411,552 is granted for a period of one year from the original expiration date of the patent.

April 12, 2012

Date



David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office