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Eldora L. Ellison
Sterne, Kessler, Goldstein & Fox P.L.L.C
1100 New York Avenue NW
Washington DC 20005

In Re: Patent Term Extension
Application for
U.S. Patent No. 8,008,449

SEP 11 2018

Dear Ms. Ellison:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 8,008,449 for a period of 552 days. 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 as necessary.

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-0909, or by e-mail at ali.salimi@uspto.gov.

Ali Salimi
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Food and Drug Administration
CDER, Office of Regulatory Policy
10903 New Hampshire Avenue,
Bldg. 51 Room 6250
Silver Spring MD 20993-0002

RE: OPDIVO® (nivolumab)
Docket No.: FDA-2016-E-0616

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

(12) CERTIFICATE EXTENDING PATENT TERM
UNDER 35 U.S.C. § 156

(68) PATENT NO. : 8,008,449
(45) ISSUED : August 30, 2011
(75) INVENTOR : Korman et al.
(73) PATENT OWNER : E.R. Squibb & Sons, L.L.C. and Ono
Pharmaceutical Co., Ltd.
(95) PRODUCT : OPDIVO ® (nivolumab)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 8,008,449 based upon the regulatory review of the product OPDIVO ® (nivolumab) by the Food and Drug Administration. According to United States Patent and Trademark Office records, the original expiration date of the patent as of the date of issuance of this certificate is June 19, 2027. Because it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 552 days

subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156.



I have caused the seal of the United States Patent and Trademark Office to be affixed this 6th day of September 2018.

Andrei Iancu

Andrei Iancu
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office