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

MAR 14 2018

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 8,008,449, claims of which cover biological human product known by tradename OPDIVO® (nivolumab), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 552 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 552 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of December 2, 2016 (81 Fed. Reg. 87044), would be 679 days. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \text{RRP} - \text{PGRRP} - \text{DD} - \frac{1}{2} (\text{TP} - \text{PGTP})^1 \\ &= 3,071 - 1,860 - 0 - \frac{1}{2} (2,925 - 1,860) \\ &= 679 \text{ days (1.9 years)}\end{aligned}$$

Since the regulatory review period began July 28, 2006, before the patent issued (August 30, 2011), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From July 28, 2006, to and including August 30, 2011, is 1,860 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

¹ Consistent with 35 U.S.C. § 156(c), “RRP” is the total number of days in the regulatory review period, “PGRRP” is the number of days of the RRP which were on and before the date on which the patent issued, “DD” is the number of days of the RRP that the applicant did not act with due diligence, “TP” is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and “PGTP” is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of $\frac{1}{2} (\text{TP} - \text{PGTP})$.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation, because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 679 days, would extend the patent from June 19, 2027, to April 28, 2029, which is beyond the 14-year limit (the approval date is December 22, 2016, thus the 14 year limit is December 22, 2028). The period of extension is thus limited to 552 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, June 19, 2027, to and including December 22, 2028, or 552 days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	8,008,449
Granted:	August 30, 2011
Original Expiration Date ² :	June 19, 2027
Applicant:	Korman et al.
Owner of Record:	E.R. Squibb & Sons, L.L.C. and Ono Pharmaceutical Co., Ltd.
Title:	HUMAN MONOCLONAL ANTIBODIES TO PROGRAMMED DEATH 1(PD-1) AND METHODS FOR TREATING CANCER USING ANTI-PD-1 ANTIBODIES ALONE OR IN COMBINATION WITH OTHER IMMUNOTHERAPEUTICS
Product Trade Name:	OPDIVO ® (nivolumab)
Term Extended:	552 days
Expiration Date of Extension:	December 22, 2028

²Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence from applicant with respect to this matter should be submitted via the USPTO's EFS Web system and should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to Ali Salimi at (571) 272-0909.



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for Patent Examination Policy

cc: FDA, CDER, Office of Regulatory Policy
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Attention: Beverly Friedman

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