



Mailed: JUN 21, 2004

Richard S. Barth  
FRISHAUF, HOLTZ, GOODMAN & CHICK PC  
767 Third Ave - 25th Floor  
New York NY 10017-2023Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,616,599

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,616,599, which claims the human drug product BENICAR® (olmesartan medoxomil), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 755 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 755 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 July 31, 2003 (68 Fed. Reg. 44954), under 35 U.S.C. § 156(c) would be:

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase) + Approval Phase} \\ &= \frac{1}{2} (1,882 - 670) + 640 \\ &= 1,246 \text{ days}\end{aligned}$$

Since the regulatory review period began June 1, 1995, before the patent issued (April 1, 1997), 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 June 1, 1995 to April 1, 1997 is 670 days; this period is subtracted for 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.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation, however 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, 1,246 days, would extend the patent from April 1, 2014 (35 U.S.C. § 154) to August 29, 2017, which is beyond the 14-year limit (the approval date is April 25, 2002, thus the 14 year limit is April 25, 2016). The period of extension is thus limited to April 25, 2016, 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, April 1, 2014, to and including April 25, 2016, or 755 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

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

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|---|---|
| U.S. Patent No.:                        | 5,616,599   |
| Granted:                                | April 1, 1997   |
| Original Expiration Date <sup>1</sup> : | April 1, 2014   |
| Applicant:                              | Hiroaki Yanagisawa, et al.  |
| Owner of Record:                        | Sankyo Company, Limited   |
| Title:                                  | Angiotensin II Antagonist 1-Biphenylmethylimidazole Compounds and Their Therapeutic Use |
| Classification:                         | 514/381   |
| Product Trade Name:                     | BENICAR® (olmesartan medoxomil)   |
| Term Extended:                          | 755 days  |
| Expiration Date of Extension:           | April 25, 2016  |

Any correspondence with respect to this matter should be addressed as follows:

|          |   |         |   |
|----------|---|---------|---|
| By mail: | Commissioner for Patents<br>Mail Stop Patent Ext.<br>P.O. Box 1450<br>Alexandria, VA 22313-1450 | By FAX: | (703) 872-9411<br>Attn: Office of Patent Legal Administration |
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Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

/s/

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Karin Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
HFD - 13  
5600 Fishers Lane  
Rockville, MD 20857

RE: BENICAR® (olmesartan medoxomil)  
FDA Docket No. 02E-0339

Attention: Claudia Grillo

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<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).