

EXHIBIT H

**STATEMENT ASSERTING ELIGIBILITY
OF U.S. PATENT 5,610,163
FOR EXTENSION**

In the opinion of the Applicant, U.S. Patent No. 5,610,163 is eligible for extension under the provisions of 35 U.S.C §156.

- (1) The term of this patent has not expired before this application is being submitted.
- (2) The Term of this patent has never been extended.
- (3) This application for patent term extension is submitted by an authorized agent of the record owner of the subject patent, Boehringer Ingelheim KG.
- (4) The product has been subject to a regulatory review period before commercial marketing or use as evident from the information set forth in numbered paragraph 11 of the application for patent term extension.
- (5) The permission for commercial marketing or use of the product after the regulatory review period is the first commercial marketing or use permission for the product under the provisions of Federal Food, Drug and Cosmetic Act.
- (6) Applicant believes that the subject patent is entitled to **1,421 days** of extension.

The claimed extension has been calculated in the manner set forth in 37 C.F.R. §1.775.

Initially, the length of the regulatory review period was determined as set forth in 37 C.F.R. §1.775 (c). It is 3,284 days, which is the sum of:

- (1) **2506 days**, the number of days in the period beginning on **2 February 1995**, the date the exemption under subsection (i) of section 505 of the Federal Food, Drug and Cosmetic Act for the approved product (IND No. 46, 687) become effective for the approved product and ending on **13 December 2001**, the date the application (NDA 21-395) was initially submitted for such product under section 505(b) of the Federal Food, Drug and Cosmetic Act; and
- (2) **778 days**, the number of days in the period beginning on **13 December 2001**, the date the application (NDA 21-395) was initially submitted for the approved product under subsection (b) of section 505 and ending on **30 January 2004**, the date such application was approved under such section.

Next, the term of the patent as extended was determined in accordance with 37 C.F.R. §1.775 (d), by:

(1) subtracting from 3,284 days, the number of days calculated above to be in the regulatory review period, **1,253 days**, which is the sum of the periods set forth in 37 C.F.R. §1.775 (d)(1)(i), (ii) and (iii), as set forth in the following Table 1 below,

Table 1	
(i) the number of days in the periods of paragraphs (c)(1) and (c)(2) of 37 C.F.R. §1.775 which were on and before the date on which the patent issued	0 days
(ii) the number of days in the periods of paragraphs (c)(1) and (c)(2) of 37 C.F.R. §1.775 during which it is determined, under 35 U.S.C. 156(d)(2)(B) by the Secretary of Health and Human Services that the Applicant did not act with due diligence	0 days
(iii) one-half of the number of days remaining in the period defined by paragraph (c)(1) of 37 C.F.R. §1.775 after that period is reduced in accordance with paragraphs (d)(1)(i) and (ii) of 37 C.F.R. §1.775 (ignoring half days for the purposes of subtraction)	1,253 days

Which calculation yields **2,031 days** as its result;

(2) adding the number of days determined in accordance with 37 C.F.R. §1.775 (d)(1), **2,031 days**, to the original term of the patent as shortened by any terminal disclaimer (which term will expire on 11 March 2014), which calculation yields **2 October 2019** as it results;

(3) adding 14 years to **30 January 2004**, the date of the approval of the application under subsection (b) of section 505 of the Federal Food Drug and Cosmetic Act, which calculation yields **30 January 2018** as a result;

(4) comparing **2 October 2019** and **30 January 2018**, the dates for the end of the periods obtained pursuant to 37 C.F.R. §1.775 (d)(2) and (d)(3), respectively, with each other and selecting the earlier date, which comparison yields **30 January 2018** as its result; and

(5) (as the original patent was issued after September 24, 1984)

(i) by adding five (5) years to **11 March 2014**, the original expiration date of the patent or any earlier date set by terminal disclaimer, which calculation yields **11 March 2019** as its result; and

(ii) by comparing **30 January 2018** and **11 March 2019** the dates obtained pursuant to 37 C.F.R. §1.775 (d)(4) and (d)(5)(i) with each other and selecting the earlier date, which

comparison yields **30 January 2018** as its result (the new expiration date after extension).

The difference between 11 March 2014, the original expiration date of the patent, and 30 January 2018, the new expiration date of the patent, is **1421 days**.