PHARMACEUTICAL LAW GROUP PC
AT THE INTERSECTION OF FDA REGULATION AND INTELLECTUAL PROPERTY
900 SEVENTH STREET, NW - SUITE 650 - WASHINGTON, DC 20001-3886
T 202 589 1780 F 202 318 2198 WWW.PHARMALAWGRP.COM

October 9, 2008

New Exclusivities for Old Antibiotics

Transitional Rules Require Prompt Action by Early December 2008

President Bush signed into law yesterday S.3560, an act to amend Title XIX of the Social Security Act, which contained provisions to enhance the ability of so-called "old" antibiotic products to take advantage of data exclusivity, Orange Book listings, and other procedural protections of the Hatch-Waxman Act.

Background: The Food and Drug Administration Modernization Act of 1997 (FDAMA) eliminated the differences in the regulation of antibiotics and other drugs. Prior to FDAMA, antibiotics were approved under section 507 of the Federal Food, Drug, and Cosmetic Act (FDC Act), and most other drugs were approved under section 505 of the FDC Act. Drugs approved under section 505 were eligible for the data and patent protections provided by the Hatch-Waxman Act – namely, protection of innovative data for three or five years, listing of relevant patents in the Orange Book, and procedural protections during patent challenges by generic drug manufacturers. Antibiotics approved under section 507 did not receive these benefits of the Hatch-Waxman Act.

FDAMA eliminated this distinction for antibiotics and other drugs approved after its effective date, November 21, 1997. As part of FDAMA, Congress repealed section 507 and included a transition provision to distinguish between "old" antibiotics that do not get the benefit of the Hatch-Waxman Act and "new" antibiotics that receive the full benefits of the Hatch-Waxman Act. FDA interpreted the statutory language of the transition provision to mean that "old" antibiotics included any new product that contained an active ingredient that had been approved (or had been the subject of an application submitted) under section 507.

The consequence of FDA's interpretation was that new and improved products containing previously approved active ingredients (or closely related salts and esters) would not get the benefit of the Hatch-Waxman Act. Such products included: (a) new active ingredients (for example salts or esters of previously

approved active ingredients that have improved therapeutic properties); (b) combination products containing old active ingredients in combination with new ingredients that have synergistic effects; (c) new uses of old active ingredients to treat new types of infections or infestations; and (d) new uses of old active ingredients to treat other conditions, such as cancer and arthritis.

S.3560: The new provisions address several shortcomings of the transition provision in FDAMA (see attachment).

I. For product applications submitted under section 505(b) of the FDC Act after the enactment of S.3560 ("post-enactment"):

A. if the drug that is the subject of the application contains an antibiotic that was approved under former section 507, then:

1. The sponsor of the drug is eligible for 3-year data exclusivity.

2. Other provisions of the Hatch-Waxman Act (such as Orange Book listings, patent certifications, etc.) apply.

3. The statutory language excludes the application of patent extensions and other exclusivities to these products. [NOTE: it is not likely that any relevant patents would meet the criteria for patent term restoration.]

4. The data exclusivity provisions do not apply to any condition of use that was approved before the enactment of S.3560 ("pre-enactment").

B. if the drug that is the subject of the application contains an antibiotic that was included in one or more applications submitted to FDA under former section 507, but was never approved, then:

1. The sponsor of the drug may elect to be eligible for:

a. 3-year or 5-year exclusivity; OR

b. patent term restoration under 35 USC 156.

2. If the sponsor elects 3-year or 5-year exclusivity, then other provisions of the Hatch-Waxman Act (such as Orange Book listings, patent certifications, etc.) apply.

3. The data exclusivity provisions do not apply to any condition of use that was approved pre-enactment.

II. Transitional Rules – Orange Book listings and Patent Certifications:

NOTE: ***Although the language is subject to interpretation, the transitional rules appear to apply to all pre-enactment pending and approved applications that contain old antibiotics which were approved under former Section 507.***

A. With respect to any patent issued pre-enactment, sponsors have 60 days after the enactment of S.3560 to file any patents in accordance with the patent listing provisions of section 505 of the FDC Act.

B. If the patent information is filed within 60 days; then, FDA shall publish the patent information in the Orange Book within 90 days after enactment.

C. If the sponsor files the required patent information within 60 days, then any pending generic applicant (under section 505(j) of the FDC Act) that amend its application within 120 days after enactment to contain the required patent certifications will be considered a first-to-file generic applicant.

Summary: S.3560 provides that any antibiotic product approved after its enactment will be eligible for the benefits of the Hatch-Waxman Act. The new provision eliminates barriers to the development of antibiotic drugs that incorporate active ingredients which were approved in other products before 1997. Accordingly, manufacturers have much greater incentive to develop certain new products that can treat or cure infections, that can increase the effectiveness of these existing antibiotics, and that can overcome bacterial resistance. Moreover, the Transitional Rules provide the opportunity for old antibiotics that are the subject of pending or approved applications to obtain Orange Book listings, patent certifications, and associated protections of the Hatch-Waxman Act. However, in order to take advantage of these Transitional Rules, companies must act promptly.

For assistance in addressing the strategic implications of S.3560, please contact Gregory J. Glover, MD, JD, Gregory.Glover@PharmaLawGrp.com, 202 589 1781.

ATTACHMENT – SECTION 4 of S.3560

http://www.thomas.gov/cgi-bin/query/C?c110:./temp/~c110tm9nhw

SEC. 4. INCENTIVES FOR THE DEVELOPMENT OF, AND ACCESS TO, CERTAIN ANTIBIOTICS.

(a) In General- Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

`(v) Antibiotic Drugs Submitted Before November 21, 1997-

`(1) ANTIBIOTIC DRUGS APPROVED BEFORE NOVEMBER 21, 1997-

`(A) IN GENERAL- Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable.

`(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED-

`(i) APPLICATION- An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

`(ii) ANTIBIOTIC DRUG- An antibiotic drug described in this clause is an antibiotic drug that was the subject of an application approved by the Secretary under section 507 of this Act (as in effect before November 21, 1997).

`(2) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997, BUT NOT APPROVED-

`(A) IN GENERAL- Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) may elect to be eligible for, with respect to the drug--

`(i)(I) the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; and

`(II) the 5-year exclusivity period referred to under clause (ii) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; or

`(ii) a patent term extension under section 156 of title 35, United States Code, subject to the requirements of such section.

`(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED-

`(i) APPLICATION- An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

`(ii) ANTIBIOTIC DRUG- An antibiotic drug described in this clause is an antibiotic drug that was the subject of 1 or more applications received by the Secretary under section 507 of this Act (as in effect before November 21, 1997), none of which was approved by the Secretary under such section.

`(3) LIMITATIONS-

`(A) EXCLUSIVITIES AND EXTENSIONS- Paragraphs (1)(A) and (2)(A) shall not be construed to entitle a drug that is the subject of an approved application described in subparagraphs (1)(B)(i) or (2)(B)(i), as applicable, to any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1)(A) or (2)(A).

`(B) CONDITIONS OF USE- Paragraphs (1)(A) and (2)(A)(i) shall not apply to any condition of use for which the drug referred to in subparagraph (1)(B)(i) or (2)(B)(i), as applicable, was approved before the date of the enactment of this subsection.

`(4) APPLICATION OF CERTAIN PROVISIONS- Notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997, or any other provision of law, and subject to the limitations in paragraphs (1), (2), and (3), the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply to any drug subject to paragraph (1) or any drug with respect to which an election is made under paragraph (2)(A).'.

(b) Transitional Rules-

(1) With respect to a patent issued on or before the date of the enactment of this Act, any patent information required to be filed with the Secretary of Health and Human Services under subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to be listed on a drug to which subsection (v)(1) of such section 505 (as added by this section) applies shall be filed with the Secretary not later than 60 days after the date of the enactment of this Act.

(2) With respect to any patent information referred to in paragraph (1) of this subsection that is filed with the Secretary within the 60-day period after the date of the enactment of this Act, the Secretary shall publish such information in the electronic version of the list referred to

at section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) as soon as it is received, but in no event later than the date that is 90 days after the enactment of this Act.

(3) With respect to any patent information referred to in paragraph (1) that is filed with the Secretary within the 60-day period after the date of enactment of this Act, each applicant that, not later than 120 days after the date of the enactment of this Act, amends an application that is, on or before the date of the enactment of this Act, a substantially complete application (as defined in paragraph (5)(B)(iv) of section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j))) to contain a certification described in paragraph (2)(A)(vii)(IV) of such section 505(j) with respect to that patent shall be deemed to be a first applicant (as defined in paragraph (5)(B)(iv) of such section 505(j)).