PCMA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

October 19, 2007

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
HFA-305
Rockville, MD 20852

Re: Docket No. 2007N-0382/Approval of Lupin ANDA for Ramipril Oral Capsules

To Whom It May Concern:

The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, and Medicare Part D. Our member PBMs provide high quality drug care at the lowest possible prices. As such, we have a strong interest in making safe, effective and affordable pharmaceuticals available to American consumers as quickly as possible. For this reason PCMA supports access to generic products generally and, in this instance, to generic Ramipril.

PCMA believes that the first to file with a Paragraph IV certification should not have the right to the Hatch Waxman exclusivity in the even that they fail to pursue the patent challenge, acknowledge infringement and work with the brand company to extend the monopoly of the brand. For this reason, we fully support Lupin Pharmaceuticals' petition for immediate approval of their ANDA No. 77-626 for Ramipril capsules.

For many years, King Pharmaceuticals has been the only supplier of Ramipril oral capsules. Because no generic has been available, the price of Ramipril has remained high. The brand name version of Ramipril capsules, Altace, is one of the top 75 medications sold nationwide. According to data from Drug Store Management, U.S. sales of Altace at the wholesale level are approximately $900 million annually. There is currently no generic version of Altace available. Our member companies' experience has proven that even one competitor for a given drug will significantly reduce the price for that drug.

The first generic application for Ramipril was filed by Cobalt Pharmaceuticals, Inc (Cobalt) on November 26, 2002. Cobalt filed a paragraph IV certification with its ANDA application. As the first to file an ANDA with a paragraph IV certification, Cobalt became eligible for 180 days of generic exclusivity. This means that no generic competitor can be approved until 180 days after Cobalt launches Ramipril capsules or there is a court decision finding that King's patent is invalid or not infringed.

Cobalt did not litigate the King's patent validity nor did it launch its generic Ramipril capsules when they were approved in October 2005. Instead, Cobalt entered into a settlement with King that allowed King to remain on the market as the only supplier of Ramipril in exchange for a substantial payment to Cobalt. Despite Cobalt's failure to litigate or launch, Cobalt and King apparently take the position that Cobalt's Paragraph IV certification blocks other generics from entering the market.

Lupin Pharmaceuticals, Inc. (Lupin) also filed an ANDA with a paragraph IV certification challenging King's patents. Unlike Cobalt, Lupin pursued its patent challenge in court. In September of this year, after years of litigation, Lupin obtained a decision in its favor. The court found that the King patent was invalid. A court decision triggers the commencing of any generic exclusivity that might be granted. As a result of Lupin's efforts, FDA will be able to grant final approval for applications for generic Ramipril immediately if there is no generic exclusivity or after 180 days if Cobalt is still entitled to generic exclusivity. [1]

Lupin, with its successful challenge to the King patent, should not be blocked by the180-day exclusivity granted to the company (Cobalt) that not only failed to challenge the patent, but also entered into an agreement designed to further delay generic market entry. The purpose of 180-day exclusivity is to award generic companies for the time, expense and effort of challenging a potentially invalid patent. Congress surely did not intend to reward a company that knowingly and purposefully circumvents these goals.

In its September 25, 2007 letter, Lupin requested that FDA approve its ANDA immediately. PCMA fully supports Lupin's request and agrees with the arguments set forth in the September 25, 2007 letter submitted by the law firm of Buc and Beardsley on behalf of Lupin. For the reasons set forth in the September 25, 2007 letter, Cobalt is not eligible for 180 days of generic exclusivity. If FDA awards Cobalt the 180 days of exclusivity, it will be creating an environment that discourages ANDA applicants that are not first to file from challenging potentially invalid patents.

PCMA also agrees that for the reasons set forth in the September 25 letter, Lupin is entitled to immediate approval. If this gives Lupin a head start on the market, that head start is well deserved because Lupin, consistent with the purpose and intend of Hatch Waxman, cleared the path for generic entry of Ramipril.

Thank you for your consideration of this important matter.

Sincerely,

Missy Jenkins
Senior Vice President, Federal Affairs

---

[1] Several other generic companies submitted ANDAs for Ramipril capsules and received tentative approval. According to Lupin's September 25, 2007 letter, it is likely that these other companies filed paragraph III certifications with their ANDAs. But for Lupin's successful patent challenge, these ANDAs could not have been approved prior to the expiration of the patent.