



From the desk of:

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Cecelia Parise, Regulatory Policy Advisor
Office of Generic Drugs

c/o Dockets Management Branch
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Re: Ramipril Capsules and 180-day generic drug exclusivity
FDA Docket No. 2007N-0382

And

Petition for Stay of Action (PSA)

Dear Ms. Parise:

In further response to the above docket regarding generic ramipril capsules, we draw your attention to subsequent events that call into question whether Cobalt will pre-empt any agency action by launching its generic capsule prior to FDA making any decision on the exclusivity forfeiture. We also file this as a PSA to stay approval of any Cobalt ANDA or others.

Action Requested

Please stay Agency approval of any ANDA related to any generic ramipril capsule until a decision is made by the FDA and/or a court of law from which no further appeal may be taken.

Statement of Grounds

Under 21 C.F.R. 8 10.35(e), FDA must grant a stay of action if all of the following criteria are met:

- (1) the petitioner will otherwise suffer irreparable injury;
- (2) the petitioner's case is not frivolous and is being pursued in good faith;
- (3) the petitioner has demonstrated sound public policy grounds supporting the stay; and
- (4) the delay resulting from the stay is not outweighed by public health or other public interests.

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Here it is plain that all criteria are satisfied. Apotex is one of many generic companies that have a clear interest in the proper resolution of exclusivity issues, especially where the FDA itself has invited comment. Apotex, among others, would be irreparably harmed by a pre-emptive strike because it might moot the Agency decision and thereby moot an important decision and the contributing jurisprudence. The PSA is not frivolous because it addresses precisely the very question the FDA invited companies, like Apotex, to opine. There are sound public policy grounds to support the stay for the very reasons the FDA opened the Docket in the first place. There is no prejudice to Cobalt because, as Apotex believes, it has nothing to delay. But the delay is important because it provides full clarity to the legal issues pronounced and opens the door to widespread generic competition that benefits the public. "The public's interest in 'the faithful application of the laws' outweigh[s] its interest in immediate access to [a competing] product." *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998). Cobalt cannot be heard to complain as it had received final launch approval, could have launched with the so-called 180-Day exclusivity, but did not do so. (See Exhibit 1 – Cobalt Approval letter dated 24 Oct. 2005). Cobalt settled its case months *later* on or about 04 April 2006.

Background

As you know, Cobalt was ostensibly the first to file against ramipril and challenge the patents, but laid down its sword to allow itself to be skewered by King Pharmaceuticals, the brand company. The current docket relates to whether voluntarily laying down on the battlefield and voluntarily being skewered still allows the victim to protest that he is still fighting the patent and thus can maintain its 180-Day exclusivity. For the reasons stated in the Docket by Apotex and others, one cannot charge the battlefield, beat its shield with the sword, and when the brand company attacks to then fall down, open yourself to attack, die on the sword, and then somehow (with a straight face) allege that you still have the fight left.

Alternatively, Cobalt cannot maintain its Paragraph IV certification because it is deemed converted to a Paragraph III or is deemed defective. It is well-established that an ANDA must be correct in all its constituents, including the patent certification section. The predicate is that the certification is correct. When it settled the lawsuit, Cobalt cannot maintain its Paragraph IV certification in good faith. Accordingly, the ANDA contains a material defect. No ANDA may be approved unless that material defect is cured. The cure is either a conversion of the Paragraph IV certification to Paragraph III (or II) or withdrawal of the Paragraph IV certification.

Knowing this, Cobalt is potentially planning to circumvent the FDA decision of Cobalt's death by launching something early.

According to King's recent 10-Q SEC filing, part of the Cobalt-King settlement agreement was that Cobalt would be the authorized generic for King. Apparently that agreement also stated that Cobalt could send a 30-Day notice letter to inform King that Cobalt intended to sell a generic product after that 30-Day notice. King apparently received that letter on or about 12 October 2007 and therefore, the 30-Day deadline is on or about 12 November 2007. (See Exhibit 2 – King's recent 10-Q, in relevant part).

According to King's 10-Q, "Pursuant to the dismissal agreement, on October 12, 2007, Cobalt sent the Company 30-day written notice of its intent to launch its generic ramipril product which product would not be supplied by the Company." As such, King does not intend to supply Cobalt with generic ramipril. Where will Cobalt get its products? It cannot be from its own ANDA because the FDA website lists the Cobalt ANDA as "DISCONTINUED." Therefore, because Cobalt has no approvable ANDA and that King is not intending to supply Cobalt, Cobalt cannot launch anything. To the extent Cobalt has something to launch, then clearly it is launching before FDA makes its decision on whether others can co-launch with Cobalt.

Currently Teva, Purepac, Sandoz, Roxane, and Dr. Reddy's have tentative approval and have a vested interest in knowing whether Cobalt is entitled to launch alone and enjoy the 180-Day exclusivity or whether these companies are entitled to compete head-to-head on Day 1 with Cobalt because Cobalt has no 180-Day exclusivity. (See Exhibit 3 – Copy of Approval website, visited 12 Nov. 2007). In addition, any pending ANDA applicant that is almost approvable has the right to know whether it will obtain tentative approval because FDA ruled that Cobalt has the 180-Day exclusivity or whether that company will receive full launch approval and enter the market at that time.

Or, Cobalt may intend to selectively waive its 180-Day exclusivity in favor of either Teva, Purepac, Sandoz, Roxane or Dr. Reddy so that any of those companies will launch and share royalties with Cobalt. In this regard, this is also wrong because the predicate to selective waiver is that there is something to waive. Until the FDA decides whether Cobalt has the 180-Day, there is nothing to selectively waive. Cobalt does not have an active ANDA pending and thus its only ability to get a product on the market is through King, which said it would not supply, or through a selective waiver, which does not apply since there is nothing to waive.

We therefore request that the FDA deny Cobalt any approvals to launch any generic product until the FDA makes an informed and timely decision on whether Cobalt forfeited or relinquished any 180-Day exclusivity it may have had.

Conclusion:

For the reasons set forth above, please take action in accordance with this.

Sincerely,



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Cc: Elizabeth Dickinson, Gary Buehler, Jeffrey Senger