UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of the Director
Bureau of Competition

Statement of Bureau of Competition Director Richard Feinstein on the Commission's Final Consent Order in *In the Matter of Teva Pharmaceutical Industries Ltd. and Cephalon, Inc., File No. 111 0166, Docket No. C-4335*
July 2, 2012

Today the Commission voted to modify and adopt as final a consent order addressing Teva Pharmaceutical Industries' acquisition of Cephalon. When the Commission adopted a proposed consent order addressing the acquisition in October 2011, available evidence indicated that multiple independent firms were positioned to launch generic versions of Provigil – a critical wakefulness drug used by those who suffer from narcolepsy – on April 6, 2012. As highlighted in the recent case of *Mylan Pharmaceuticals v. Sebelius*, that did not happen.[1] Instead, Teva was awarded sole 180-day generic marketing exclusivity for generic Provigil. Only Teva, in the form of an authorized generic product, and Par Pharmaceuticals, supplied by Teva under the terms of the Commission's proposed consent order, have launched generic products to date.

As detailed in the FTC's recent *amicus* brief in the *Mylan* case, this development raised two concerns.[2] First, there had been indications that Teva believed, contrary to what the FDA had stated, that Teva's launch of an authorized generic product had not triggered its 180-day exclusivity period. If Teva's position on this issue were to prevail, further generic Provigil entry could be substantially delayed, resulting in significant consumer harm. Second, the terms of the Commission's October 2011 proposed consent order were designed for a market with multiple independent generic competitors. While Par has launched a generic product, Par is entirely dependent on Teva – which also markets branded Provigil – for supply and does not have the ability to turn to alternate sources of supply in the near future. This market dynamic is not likely to replicate one in which an independent competitor was marketing generic Provigil.

The final consent order resolves the first of these two concerns: Teva has unequivocally agreed that it will not challenge the FDA's determination that the 180-day exclusivity period for generic Provigil began to run on March 30, 2012. This provision benefits consumers by assuring that the FDA will be able to approve additional companies seeking to market generic Provigil when the 180-day exclusivity period expires in September 2012. Estimates presented in the Commission's 2011 Authorized Generic Report indicate that the wholesale price of generic

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[1] *Mylan Pharmaceuticals, Inc. v. Sebelius*, No. 12-524, 2012 WL 1388256 (D.D.C. Apr. 23, 2012) (denying Mylan motion for preliminary injunction in challenge to FDA's award of sole 180-day exclusivity to Teva).

[2] Brief of FTC as *Amicus Curiae*, *Mylan Pharmaceuticals, Inc. v. Sebelius*, No. 12-524 (D.D.C. Apr. 12, 2012), *available at* http://www.ftc.gov/os/2012/04/120411mylanamicus.pdf.

versions of a typical drug fall by approximately 50 percent following the end of the 180-day exclusivity period, and well below 50 percent of the original cost of the branded drug. If additional generic entry follows this post-exclusivity pattern, purchasers of Provigil, potentially including the federal government, may save a billion dollars or more over several years.

The Bureau of Competition had also sought to address the second concern through the entry of an independent generic competitor before the end of Teva's 180-day exclusivity period. Teva addressed this concern by entering into a license agreement with Mylan that provides for Mylan's entry as of August 10, 2012, 45 days early.[3]

[3] Mylan Inc., *Mylan Settles Provigil® Litigation With Teva* (June 8, 2012), *available at* http://investor.mylan.com/releasedetail.cfm?ReleaseID=681504.