

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CIE, BAYER PHARMA AG and)
BAYER HEALTHCARE)
PHARMACEUTICALS INC.,)
)
Plaintiffs,)
v.)
)
WATSON PHARMACEUTICALS, INC.,)
WATSON LABORATORIES, INC.,)
)
Defendants.)

C.A. No. 12-161-RGA

CONFIDENTIAL
~~FILED UNDER SEAL~~

ORDER

WHEREAS, Plaintiffs Merck & Cie, Bayer Pharma AG, and Bayer Healthcare Pharmaceuticals Inc. (collectively, "Plaintiffs"), having filed a Motion to Dismiss pursuant to Fed. R. Civ. P. 12(b)(1) on the grounds that there is no justiciable case or controversy between the parties; and

WHEREAS, a Paragraph IV Notice letter that has been sent absent a received ANDA is of no legal effect under 21 U.S.C. § 355(j)(5)(B)(iii) and 21 C.F.R. § 314.95(b), and does not invoke the 45-day window for a patent holder to file suit, nor does it commence the 30-month stay before the ANDA can be approved; and

WHEREAS, the Court having considered the Motion and finding good cause to grant it;

IT IS HEREBY ORDERED this 25th day of September, 2012, that

- (1) Plaintiffs' Motion to Dismiss the Complaint is GRANTED *and*
- (2) *The Complaint is DISMISSED WITHOUT PREJUDICE.*

~~(2) If and when the FDA accepts Abbreviated New Drug Application 203593 from Watson (including any determination that Watson's original filing should have been accepted),~~

~~or any other ANDA for a generic Beyaz™ from Watson, then Watson must provide Plaintiffs with a new Paragraph IV Notice letter to invoke the 45-day window for a patent holder to file suit, and commence the 30-month stay before the ANDA can be approved;~~

~~(3) Watson is hereby ordered to produce to Plaintiffs any further correspondence with the FDA or contact reports reflecting communications with the FDA relating to Abbreviated New Drug Application 203593 or any other ANDA for a generic Beyaz™ from Watson within 72 hours of the correspondence; and~~

~~(4) Watson is hereby ordered to submit to the FDA this Order and the underlying briefs and exhibits on Bayer's motion to dismiss.~~



United States District Judge