IP FLASH

Paul A. Calvo, PhD, Director
Sterne, Kessler, Goldstein & Fox P.L.L.C., Washington D.C.

Biosimilars in the United States – where do things stand?

BIOSIMILARS *2015 has seen a great deal of activity for biosimilars in the United States. The very first biosimilar product was approved on 6 March 2015 to Sandoz for their biosimilar product of filgrastim – to be marketed as Zarxio®. In April 2015, the US Food and Drug Administration (FDA) issued three final guidance documents on biosimilarity. These documents reiterate use of a totality of the evidence approach for review of biosimilar applications. They also encourage a stepwise approach to demonstrating biosimilarity – including comparisons in terms of structure, function, human PK/PD, clinical immunogenicity, and clinical safety/effectiveness.*

The "Purple Book" was released in 2015, which is a listing of US licensed biologicals with reference product exclusivity. This listing does not contain any patent information however, unlike its small molecule counterpart, the Orange Book.

The US Centers for Medicare and Medicaid Services (CMS) also announced their reimbursement policy for biosimilars, which will be similar to that of innovator biologics. CMS will use a formula for reimbursement designed to reduce financial incentive to prescribe more costly biologics, which is typically the reference product.

2015 has also seen state lobbying efforts to limit biosimilar market penetration. Eight states have enacted laws limiting biosimilar substitution, but at least six states are advancing legislation that would allow more flexibility by prescribing physicians and pharmacists to substitute the biologics.

2015 also has seen significant litigation in US courts surrounding the implications of the Biologics Price Competition and Innovation Act (BPCIA), the governing statute for US biosimilars. The most important decision to date comes from the Federal Circuit Court of Appeals in Amgen v. Sandoz. On 21 July 2015, a three-judge panel ruled that:

(1) the BPCIA does not require biosimilar applicants to turn over their application and manufacturing information to the reference product sponsor, thereby making it "optional" to take part in the so-called patent dance; and

(2) notice of commercial marketing is effective only once the FDA has licensed the biosimilar product for commercial marketing. The decision of the panel was not unanimous, however. There is a belief that a decision review by the entire court may be forthcoming. For now, the decision paves the way for Sandoz to launch Zarxio® after 2 September 2015 as the first US biosimilar biologic. ■

Picture: SKGF