Evaluate Vantage

March 09, 2015

FDA OK leaves market waiting for Zarxio

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Give Novartis an A for achieving the first approval via the new US biosimilar pathway, but an incomplete for actually selling the drug.

Zarxio, a copy of Amgen's Neupogen, got the blessing of the FDA last week, a watershed event in a market in which several major biologicals are counting down to their patent expiries. But the launch of the neutropenia medication cannot be executed as the group is still in court over its compliance with biosimilar law.

Do you want to dance?

The two companies will be in federal court in California on Friday to argue over an injunction sought by Amgen. The world's largest biotech wants to block the launch because Novartis's Sandoz generics division has declined to participate in patent disclosure procedures – nicknamed the "patent dance" – as required under the 2010 healthcare reform law that enabled the biosimilar pathway.

Sandoz claims that, because the law provides for legal remedies for the reference product's owner should the biosimilar sponsor not participate, the patent dance is not mandatory. The point of the disclosure is to determine whether the biosimilar maker's manufacturing processes violate any remaining patents.

The generics group has set a deadline to begin selling the drug of April 10 or conclusion of the lawsuit, whichever comes first. However, should the court side with Amgen and require the process disclosures, it is not at all clear that the Sandoz deadline would necessarily stand, because the patent dance can take up to 215 days, as outlined in the biosimilar law.

The result of this case will likely set precedent, as a decision that favours Sandoz would establish a judicial route distinct from the patent dance, something most biosimilar makers would probably follow. So far, the courts have ruled that the law should be followed.

Every day Zarxio stays off the market is worth millions of dollars in revenue to Amgen; Neupogen sold $839m in the US in 2014.

That's not my name

Zarxio's approval also has raised another point: the generic names for biosimilars. The FDA took the middle ground by appending "sndz" to the filgrastim under which Neupogen is sold.

Biosimilar makers have contended that the same name should be used to avoid confusion and enable dispensing. The innovative manufacturers have argued that different names are needed to aid tracking in the event of unexpected adverse events.

Legal manoeuvres can only delay the launch of the first biosimilar in the US, which now appears to be weeks away, and could clear the way for some weighty franchises like Herceptin and Humira to fall. Sustained innovation will be crucial to avoid a mini patent cliff for biologicals in a couple of years.

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