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Not so fast on that first US biosimilar launch

Jonathan Gardner

Biosimilars took a big step forward in early 2015 with the first US panel backing for one and a vote scheduled for another, the first monoclonal antibody copycat to seek approval.

But questions still hang over the procedures for getting to market, with legal action threatening to block the launch of Sandoz's biosimilar version of Neupogen. The case against the Novartis division could go some way towards defining the so-called “patent dance” of intellectual property disclosures, providing some clarity for future biosimilar applicants.

Antibodies coming quickly

The vote to support the Neupogen rival – called Zarxio – from Novartis’s Sandoz division was a clear sign of expert acceptance for biosimilars in the US. Now it must complete the regulatory pathway established by healthcare reform legislation enacted in 2010 (*US set for first biosimilar after unanimous Zarxio panel, January 8, 2015*).

Amgen’s Neupogen, a granulocyte colony stimulating factor, was seen as a ripe early target not just because its patent estate has been expiring but also because it is a relatively simple biological.

A bigger prize has been seen in launching biosimilar competitors to more complex monoclonal antibodies, a feat that Hospira and Celltrion are close to achieving. An advisory committee hearing is scheduled for March 17 for Remsima, their version of Johnson & Johnson and Merck & Co’s Remicade. This has been submitted for all of the indications in which Remicade is approved.

Assuming that both Zarxio and Remsima reach the market on schedule, US approval of a copycat monoclonal antibody will trail the first biosimilar approval by only months. By comparison, the first European biosimilar – a GCSF – was launched in 2006, but the first green light of a monoclonal antibody biosimilar occurred only in 2013, when patents protecting Remicade fell in this region (*EU opens door to biosimilar antibodies, June 28, 2013*).

The first US approvals, if achieved, should embolden others to follow as the signposts will be easier to see. At least one other US biosimilar application has been submitted: Hospira’s Epogen copycat Retacrit.

Bernstein analyst Ronny Gal has identified 30 programmes in phase III as of October 2014 and thus nearing the point where they could be filed in the US; big targets include the breast cancer drug Herceptin, rheumatoid arthritis drugs Rituxan and Humira, along with additional Remicade candidates. He adds that there are fewer companies pursuing simpler biosimilars such as GCSFs and Epogen.

See you in court

However Zarxio's path to market could still be complicated by pending legal action from Amgen. While Sandoz, as a generics maker, is no stranger to the courtroom the shape of judicial proceedings in the biosimilar space has not been fully determined.

At issue is the “patent dance”, the requirement under the US law that the biosimilar and reference product manufacturers exchange information on production processes to determine if they violate any unexpired patents.

Sandoz has not provided any information to Amgen, arguing that despite confidentiality safeguards it would be giving proprietary information to a competitor. It points to a section in the law providing for legal remedies for the innovative manufacturer as a sign that the patent dance is not a requirement – suggesting a second path forward whereby discloure is taken out of the reglatory frame and heard in the court room.

The case is still to be decided by a federal district court. With an approval deadline due within months, it could be that the approval could come but the launch will be delayed by injunction.

This would be a disappointment for many, but most of all for US payers hoping that the huge price cuts seen in Europe – biosimilar Remicade was introduced in Norway at a 72% discount to the original – can be replicated,

allowing them to withstand the blow of expensive new drugs.

To contact the writer of this story email Jonathan Gardner in London at jonathang@epvantage.com or follow @JonEPVantage on Twitter