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How the rushed biosimilar law is yielding go-slow launches

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If there is any lesson to be learned from the fortunes of the first agents to set foot on the new US biosimilar pathway, it is that the regulations are straightforward but the law is byzantine.

Three federal lawsuits have now been filed relating to patent disclosure requirements in the 2010 law that created the biosimilar track. Vague wording has allowed Amgen to string out the launch of lookalike Neupogen past the date of formal regulatory approval, and threatens to do the same for competitors to Remicade and Epogen if courts cannot resolve matters or legislators do not clarify the law.

These issues have emerged as a result of the history of the Biologicals Price Competition and Innovation Act (BPCIA), which was being negotiated as a standalone bill on Capitol Hill when lawmakers decided to insert it into the Patient Protection and Affordable Care Act (ACA). “As result the biosimilar draft law was inserted, only half-baked, into the law with several pro-innovator provisions,” Bernstein Research analyst Ronny Gal wrote in a recent note. “The generic side considered the law so poorly written it lobbied for its exclusion from the ACA.”

Rather than complying with the patent disclosure requirements of the law – referred to as the “patent dance” – biosimilar manufacturers have sought a potentially faster judicial end-run. The motivation to get to market quickly is particularly strong for those contesting early-generation biologics agents like Neupogen and Epogen, which were launched more than 20 years ago, says Louis Fogel, a partner in the law firm Jenner & Block.

The biosimilar makers “don’t want to go through elaborate patent dance procedures to be off the market for potentially another year,” Mr Fogel said in a recent webinar on biosimilar litigation that his firm sponsored. “If they can get through litigation faster than going through the patent dance, the generic companies are going to want to do that.”

Jumping the gun

This was, in fact, the motivation behind the first BPCIA-related lawsuit, a 2013 action taken by Novartis’s Sandoz division seeking a judgement that its version of Enbrel was not in violation of any enforceable patents. The action came the same day as initiation of its phase III trial; the courts decided that because Sandoz had not filed an application for regulatory approval it was not in a position to judge whether infringement had occurred.

The two most recent lawsuits have related to active applications: Amgen fighting Sandoz’s Neupogen rival, called Zarxio, and Johnson & Johnson fighting Celltrion and Hospira’s Remicade copy, called Remsima or Inflectra.

Two issues are being contested. First, the BPCIA required that the biosimilar manufacturers give the branded drug owners 180-days’ notice that they intend to market a competitor, a period of time intended to enable the resolution of IP disputes - the patent dance - ahead of a regulatory decision. But because the language in the law uses the term “licensed”, Amgen and J&J argue that the 180-day notice cannot be provided any earlier than the day of FDA approval – in the case of Zarxio, March 6 (*FDA OK leaves market waiting for Zarxio, March 9, 2015*).

The biosimilar makers contend that the wording could not have been intended to provide an additional six months of market exclusivity. For this reason, Bernstein’s Mr Gal writes that this dispute “should break for the biosimilars”, although he acknowledges that it might not do so because of the unclear wording.

Dancing the patent away

The second issue is whether the BPCIA mandates participation in the patent dance; as well as providing pre-launch IP resolutions this process was intended to avert any damages resulting from an at-risk launch. Sandoz and Celltrion argue that the exchange is optional, because the law provides for a judicial alternative if a company refuses to take part; Amgen and J&J argue that use of the word “shall” means that it is required.

A federal district court in California last week heard arguments in Amgen’s motion for an injunction in the

Neupogen-Zarxio case, meaning a decision could come any time. If the judge sides in favour of Amgen, it is likely that Zarxio's debut will be delayed well past April 10, the date on which Sandoz has pledged to launch.

Indeed, the patent dance can take up to 215 days – the innovative product manufacturer is given up to 120 days over two rounds to review the biosimilar makers' documents. At $839m in US sales in 2014 for Neupogen, or $2.3m a day, Amgen has every incentive to take all 120 days.

Mr Gal predicts that the courts will decide in favour of the branded manufacturers because the law intended to offer the patent disclosure as a trade-off for an abbreviated regulatory pathway.

Separately, Amgen last year filed a citizens' petition with the FDA asking the agency to require that biosimilar manufacturers comply with the patent dance. Given the controversy surrounding this issue, it is likely that the FDA will defer to the courts.

Given the advanced stage of the Neupogen litigation, the sector should find out federal judges' interpretations of the law in the coming weeks. In the absence of congressional action to clean up the BPCIA's language, these rulings should guide the next set of biosimilar applicants.

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