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Biosimilar notice may precede approval in US

Biosimilar applicants in the US may provide the statutory 180-day notice of commercial marketing before they obtain approval from the US Food and Drug Administration (FDA), the US Supreme Court has stated in a unanimous decision favouring Sandoz over Amgen. Furthermore, the requirement in the US Biologics Price Competition and Innovation Act (BPCIA) for biosimilar sponsors to provide the reference-brand owner with their application and manufacturing information "is not enforceable by an injunction under federal law", but may be so under state competition law.

Sandoz and Amgen had disagreed over the meaning of Section 262(l)(8)(A) in the BPCIA, which states that a biosimilar applicant "shall provide notice to the reference-product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)". The Federal Court of Appeals had sided with Amgen in finding that this meant the 180-day notice could only be given after the biosimilar had been approved by the FDA, and had granted an injunction that delayed Sandoz' launch of its Zarxio (filgrastim-sndz) rival to Amgen's Neupogen (**Generics *bulletin***, 7 August 2015, page 1).

But the Supreme Court overturned that finding. "Because the phrase 'of the biological product licensed under subsection (k)' modifies 'commercial marketing' rather than 'notice'," it stated, "'commercial marketing' is the point in time by which the biosimilar must be licensed." Had Congress intended to make two timing requirements – FDA approval and notice 180 days before launch – "it presumably would have done so expressly" as elsewhere in the BPCIA.

Addressing whether providing the application and manufacturing information was obligatory and enforceable by injunction, the Supreme Court said the Court of Appeals had reached the right conclusion, but on flawed reasoning. The remedy provided by Section 262(l)(9)(C) of the BPCIA – allowing the originator to bring an immediate declaratory-judgement action for artificial infringement – "excludes all other federal remedies, including injunctive relief", found the Supreme Court, which ordered the Court of Appeals to rule on whether failure to provide information was "unlawful" under Californian competition law.

Stada acquisition threshold is cut

The private-equity backed vehicle proposing to take control of Stada will now see its offer succeed if at least 67.5% of all of the German firm's shares are tendered by 22 June 2017, after lowering the minimum acceptance threshold for the offer and extending by two weeks the offer's acceptance period. In April, Stada voiced its support for a €66.00 (US$74.21) per share takeover offer tabled by Bain Capital and Cinven's Nidda Healthcare Holding that valued the German group at around €5.32 billion (**Generics *bulletin***, 14 April 2017, page 1). The Nidda vehicle set an initial acceptance period with a minimum threshold of 75% of shares ending on 8 June (**Generics *bulletin***, 5 May 2017, page 3).

Stada – which has postponed until 30 August the firm's annual general meeting in light of the offer – insisted all other offer conditions would remain unchanged.

"The executive board and supervisory board will continue to recommend to the shareholders of Stada to accept the offer as it is in the best interest of the company and its stakeholders," Stada commented. "The executive board and supervisory board also think that the total compensation of €66.00 per Stada share continues to adequately reflect the enterprise value and represents the financially most attractive offer."Although Nidda's offer has been endorsed by Stada, China's Shanghai Pharmaceuticals last month admitted an interest in acquiring Stada, but denied submitting an offer (**Generics *bulletin***, 26 May 2017, page 3).