IP FLASH

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BIOSIMILARS *After a four-year wait since passage of the Affordable Care Act established an approval pathway for biosimilar biologics, 2014 has thus far seen the filing of the first two biosimilar applications with the Food and Drug Administration. On 24 July, the FDA accepted for review the very first biosimilars application, also known as a 351(k) application. It was filed by Sandoz, which is seeking approval for a biosimilar for filgrastim (Neupogen®) or G-CSF. Not long after Sandoz' filing, Celltrion submitted a 351(k) seeking approval for their biosimilar of infliximab (Remicade®) – a monoclonal antibody that binds tumor necrosis factor. Celltrion's submission is significant because it was the first filing seeking approval of a complex biologic. It is unclear whether Sandoz or Celltrion is seeking approval of their biologic as a biosimilar or as an interchangeable.*

2014 has also seen the first activity in the courts related to biosimilars. After being denied the ability to seek a declaratory judgment against Amgen related to patents covering etanercept, Sandoz appealed the district court decision to the Court of Appeals for the Federal Circuit. Sandoz is seeking the ability to challenge the validity of two patents licensed by Amgen, even though Sandoz has not submitted its biologics application for biosimilar etanercept. The Appeals Court heard oral arguments relating to that case on 10 September and a ruling is expected in the next few months. Although they have already filed their 351(k) application, Celltrion is also seeking a declaratory judgment challenging Janssen's patents related to infliximab. Janssen just recently filed a motion to dismiss the case and the court ruling should be coming soon, but likely after a ruling from the Appeals Court in Sandoz.

> US Biosimilar Biologics – the ship has sailed

Lastly, in preparation for biosimilars approvals, the FDA has released its Purple Book. The Purple Book is not meant to be an equivalent to the Orange Book for biologics. The Purple Book is simply a listing of CBER- or CDER-approved biologics or interchangeable biosimilars. The information that the Purple Book will contain includes: the BLA number, product name, date of licensure, whether the biologic is an interchangeable or biosimilar, and whether it has been withdrawn. An important difference with the Orange Book is also that there is no patent information in the Purple Book.

So while it has been slow in coming, the biosimilars ship has sailed in the United States. The success of these first filers – both at the FDA and in the courts – will be interesting to follow over the next year. The era of generic biologic drugs has officially begun. ■

Bayer refocus

LIFE SCIENCES Germany's Bayer SE said in late September that it plans to focus entirely on its life science businesses Bayer HealthCare and CropScience, and that it will float its MaterialScience unit on the stock market as a separate company within the next 12-18 months. The pharma major's life sciences business units already account for 70% of the company's turnover and 88% of its EBITDA before special items. The future Bayer Group, which had pro forma sales of about €29bn in 2013, will employ around 99,000 people. The company also said that it intends to raise R&D spending and strengthen early research. Three weeks before, the life sciences giant had already announced that it will invest about US$700m, strengthening its business with herbicides and genetically engineered seeds in the next two years. US$80m thereof will flow into a herbicide R&D centre in Sacramento, and US$200m will be used to expand operations at Bayer CropSciences R&D headquarters in North Carolina. ■

Cash injection

FUNDING Following the £56.4m divestment of next-generation sequencing world market leader Illumina last year, British firm Oxford Nanopore is well-heeled again. A private placement of ordinary shares led by new investor Woodford Investment Management LLP brought €45m (£35m) in funds in mid-August. The Oxford-based specialist for nanopore sequencing wants to use the cash to push access as well as customer support for its MINION device through its so-called MinION Access Programme (MAP). The USB flash-drive sized MINION is a first-in-class nanopore-based single molecule sequencing device. According to Oxford Nanopore, it allows ultra-fast, real-time measurements of ionic current changes when a DNA nucleotide passes through the nanopore after a voltage is set across the membrane. ■

Pictures: SKGF