The unanimous vote in January by the Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee to recommend approval of the first biosimilar to be sold in the U.S. was hailed as momentous. Biosimilars are already sold widely in Europe, where they save consumers and governments billions of dollars. An amendment to the Patient Protection and Affordable Care Act (PPACA) called the Biologicals Price Competition and Innovation Act (BPCIA)1 gave the FDA the authority to approve biosimilars. President Obama signed the PPACA in March 2010, but the FDA has been slow in providing the regulatory guidance drug companies have needed for submitting applications.

Finally, the first three biosimilar applications were submitted last summer, led by one from Novartis’ Sandoz subsidiary for a generic version of Amgen’s Neupogen (filgrastim). The FDA advisory committee voted 14–0 to recommend that the agency approve Sandoz’s version and recognize it as being “highly similar” to Neupogen. Sandoz already sells a biosimilar version of Neupogen, called Zarzio, in 40 countries.

But the FDA needs to make some key decisions surrounding the approval, and even then a lawsuit could sideline the Sandoz drug long after the FDA acts. The big question is what the FDA will allow Sandoz to call the drug in the U.S. Sandoz wants to use the same generic or nonproprietary name—filgrastim—that Amgen uses.

Because they are made from living cells, biosimilars are functional imitations of the reference drug but not exact copies, as traditional generic versions of chemical drugs can be. Amgen (which, by the way, is developing its own biosimilars) wants to highlight that distinction by forcing Sandoz to add a prefix or suffix to filgrastim. That would make it easier for the brand-name company, whether Amgen or some other company in the future, to deploy its considerable marketing machinery to convince physicians that filgrastim-XXX is not Amgen’s filgrastim.

At the January 7 advisory committee meeting, Richard Markus, Vice President of Global Development for Amgen’s biosimilar portfolio, argued for distinguishable names for biosimilars to assure accurate medical records, manufacturer accountability, and informed, appropriate use.

Sandoz wants to be able to use the international nonproprietary name (INN) for filgrastim. The World Health Organization administers the INN system, which names the active ingredient so products sharing the INN can readily be identified as sharing the same active ingredient. “A few groups are proposing changes to the well-established INN system that would apply only to biosimilars in the U.S., claiming to do so on grounds of undefined risks to patient safety,” states Elizabeth Renz, Director of Communications at Sandoz Inc. “Yet we know that any differentiator in nonproprietary names will reduce competition in the health care market and patients may have to pay more.”

The FDA has not tipped its hand. But James C. Shehan, Of Counsel, Hyman, Phelps & McNamara, P.C., who represents drug companies at the FDA (though neither Amgen nor Sandoz), points out that in the FDA staff briefing papers for the advisory committee meeting, the Sandoz drug was called “EP 2006,” not filgrastim. He thinks that may provide a clue to the FDA’s thinking—that the agency may refuse to let Sandoz use filgrastim by itself.

Another issue is “interchangeability.” Sandoz applied for approval of filgrastim as “highly similar” to Neupogen. If the FDA approves that designation, it would mean that in the event a physician wrote a prescription for Neupogen, and the patient took that prescription to a pharmacy, the pharmacy would have to call the physician for approval before substituting the Sandoz biosimilar. Sandoz could have applied for a designation of “interchangeable.” Then the pharmacist would not have to make that phone call. But an interchangeable designation requires much more clinical testing, and the FDA has not even produced a guidance document explaining what it will look for.

Complicating Sandoz’s path further is a court case filed by Amgen alleging a number of patent infringement claims. A very similar case involving the same two companies but a different drug, Enbrel, was decided last year by a U.S. District Court in California. Amgen won that case, although Sandoz had not filed a biosimilar application. A federal appellate court upheld the Amgen judgment. Shehan thinks that court case provides an indication that Amgen’s case against Sandoz for Neupogen patent infringement may also be decided in Amgen’s favor. The issues are almost identical.

Sandoz has rolled the dice. By deciding to ignore BPCIA requirements calling for it to notify Amgen of patents at issue at the time Sandoz filed its biosimilar application with the FDA, Sandoz is hoping federal courts will rule that strategy legal, allowing it to bring its version of filgrastim to market sooner than if it had met BPCIA requirements. Amgen hopes its lawsuit will succeed, delaying marketing of Sandoz’s filgrastim by years.

Will Sandoz’s gamble pay off? Other biosimilar applicants, current and present, hope so.

REFERENCE