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FDA biosimilars guidance sparks reviews of IP protection

By Lori Valigra

The U.S. Food and Drug Administration's recently issued guidance for development of biosimilars, which could take a bite out of both escalating drug prices and drug company profits, has upped the stakes for intellectual property protection at biotech and pharmaceutical companies, causing them to assess their patent positions and look at other safety devices such as trade secrets, a Boston-based patent lawyer said.

"Companies are starting to think about what to patent and what to keep as a trade secret, and how to protect a trade secret," Konstantin Linnik, an intellectual property (IP) attorney at Nutter McClennen & Fish in Boston, told Mass High Tech. Linnik was formerly a senior corporate counsel at Pfizer.

Biosimilars, also known as follow-on biologics, are products that are similar to, but not the same as, an innovative new drug. Since they are expected to cost less than an innovative drug, they bring new treatments to patients who previously could not afford them. They are not generic drugs, which are shown to be the same and generally designated as therapeutically interchangeable.The Patient Protection and Affordable Care Act, signed into law by President Obama on March 23, 2010, created an abbreviated approval pathway under section 351(k) for biosimilars and drugs that are interchangeable with an FDA-licensed biological product.

With 2014 looming as a year when a lot of drugs will come off patent, Linnik said the ensuing litigation will be very different than earlier lawsuits due to the new law. This will be both in terms of which patents will be asserted and how IP will be protected. This is especially true as companies try to get more mileage out of their blockbuster drugs by creating "biobetter" products, which are improvements the companies themselves make to existing drugs as they try to essentially extend IP protection.

"Companies are actively looking into this. For biobetter products, the improvements they make are often incremental in nature. The patent office typically rejects this, so they have to look at how get a patent on a biobetter and how broad it will be," he said.

This has brought a long-established practice, trade secrets, front and center. Most pharmaceutical companies haven't focused on trade secrets, although biotechs have used them, particularly for manufacturing processes, which often are crucial to a new drug's success. Manufacturing processes are patent eligible, but require disclosure of all information about how the invention is enabled. But that opens the door for competitors to look at the details and design around them, Linnik said.

Konstantin Linnik, IP expert at Nutter McClennen & Fish in Boston

Trade secrets, by contrast, allow a company to keep manufacturing processes from the eyes of competitors. A company must declare a trade secret, limit access

to it, make employee agreements, and monitor the protection. "It's a self-enforcement that is very effective," he said, pointing to the Coca-Cola company's secret recipe, which is kept safe by a trade secret. Trade secrets can last 100 years or more, he said, whereas a patent is effectively good for only 13 years in the pharmaceutical industry, as it starts with the product's development, which can take seven years out of the total 20 years of protection.

Linnik sees New England as a beneficiary to th new biosimilars guidance, as the biotech industry is in an upsurge compared to other places. Locally, Momenta Pharmaceuticals Inc. and STC Biologics, both of Cambridge, are developing biosimilars, and Quintiles Transnational Corp., based in North Carolina and with offices in Cambridge, early last year inked a $266 million partnership with South Korea's Samsung Group to produce biosimilars near Seoul. Late last year Biogen Idec Inc. of Weston said it and Samsung were collaborating on a $300-million joint venture to develop and market biosimilars.

The global biosimilars market is expected to hit $19.4 billion by 2014, with a compound annual growth rate of 89.1 percent from 2009 to 2014. Asia was the dominant market in 2008 because it commercialized products early, but the Americas are expected to dominate in 2014, spurred by the U.S. market opening to the products in 2010, according to researcher Markets and Markets.

But Linnik sees potential risk in creating the legislation to save money. "It could drag the whole industry down. People are focused on me-too drugs instead of innovation, though it does generate competition," he said. And for big pharma, creating biosimilars to drugs sold by competitors could be a strategic advantage.

But generally, "Any guidance out of the FDA is good because there is more certainty for products," Linnik said. A generic drug gets six months of exclusivity, so the fact that biosimilars get one year of exclusivity is huge and gives companies some certainty of a return on investment, he added.

The FDA's guidance on biosimilar product development issued on Feb. 9 contains three draft guidance documents to assist industry in developing biosimilars in the United States.

"These draft documents are designed to help industry develop biosimilar versions of currently approved biological products, which can enhance competition and may lead to better patient access and lower cost to consumers." Dr. Janet Woodcock, director of FDA's Center for Drug Evaluation and Research, said when the guidelines were released.

The three guidelines, for which the FDA is seeking public comment, are Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product, and Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009.