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Suggestions for overcoming the problems with biosimilars in the United States

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The US lags far behind Europe in authorizing BioSimilars. The problem sits squarely on the doorstep of the legal process for gaining Biosimilar approval in the US. Unlike a Generic Pharmaceutical, a BioSimilar can exhibit substantial differences from the registered Biological. Such differences give rise to the authorization difficulties but may also make the BioSimilar patentable. Clear sailing through the US Patent Office for a Biological is not assured however. For example, the U.S. Supreme Court and the Patent Office have laid down rules that restrict the patenting of natural products. Proof may be needed that a Biological composition is non-obvious in view of the Registered Biological. In this presentation the author will address will address these issues and provide suggestions for overcoming them. The legal process for gaining approval for sale of a BioSimilar in the US is two-fold: FDA approval of the BioSimilar and successfully wading through the patent quagmire protecting the Registered Biological. The FDA requirements for BioSimilar approval differ substantially from FDA requirements for approval of a Generic Pharmaceutical. Biotech companies explain that long and complicated clinicals as well as certification of the production variability of the Biological are required. The patent blockage is also difficult. Unlike the Hatch Waxman law which makes the service of the Paragraph IV letter an artificial act of infringement and which brings on the lawsuit, the BioSimilars Laws looks to the parties to initiate a patent dispute. In several recent examples, BioSimilar companies attempted to bring on the lawsuit through declaratory judgment actions only to be thrown out of court because the dispute was deemed "premature." We will discuss such flash points in the legal process for US approval of BioSimilars. Not only are Biologicals brews of several or many components but they vary from batch to batch. The US FDA recognizes this difficulty and has promulgated substantial requirements for BioSimilars approval based upon the clinicals for the Registered Biological. However, the very differences and difficulties in making safe and active products provide an opportunity to obtain US Patents for BioSimilar products. Prosecution of a BioSimilar patent application in the US has special needs and pitfalls, not the least of which are the new PTO regulations and rules concerning the patenting of natural products. While the old guideline enabled patenting of a Biological isolated from nature, no longer is this apparently possible because of Myriad and the new US Patent Office rules. Why should a BioSimilar be patented? The short answer is simple: Keep other Biological Generics from copying your product. The long answer depends upon costs, timing, profitability and assessment of the alternative to patenting: keeping the details of the BioSimilar and its process as trade secrets. Of course, the FDA approval process with its disclosure requirements undermines a manufacturer's ability to maintain these features as trade secrets. The author will discuss this balance of pros and cons for patenting versus trade secret protection.

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