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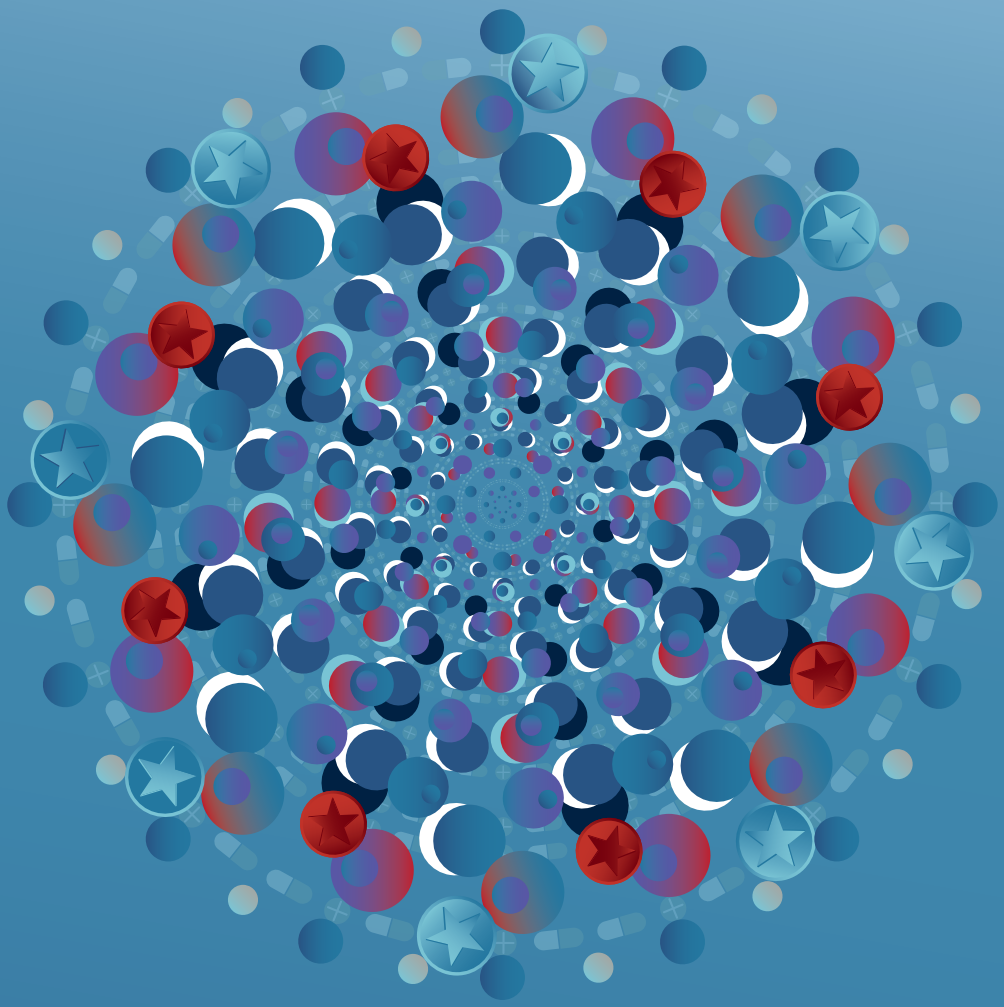

UNITED STATES BIOPHARMACEUTICALS

2018

Biopharma Superclusters - Massachusetts - San Francisco Bay Area - New Jersey
Research and Development - Contract Services - Drug Discovery
Academic Research - Regulations and Compliance - Logistics and Distribution

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Steptoe and Johnson is a 600-attorney international law firm specializing across all areas of IP, with U.S. offices located in New York City, San Francisco, Los Angeles, Washington, Chicago and Phoenix.

Steptoe & Johnson has an extensive U.S. presence, with good proximity to the major biopharma hubs. How great a focus is life sciences within the firm's portfolio?

Life sciences continues to be an important focus area for Steptoe & Johnson and its IP department. We are an approximately 600-attorney firm with offices in New York, Washington D.C., Chicago, Phoenix, San Francisco, London and Brussels.

A crucial component of successful firms in life sciences is a strong technical background to compliment a strong legal background. We are one of the few firms with robust and stable of attorneys who also have advanced life sciences degrees – 19 of the 60 attorneys in IP have advanced life sciences degrees, such as PhDs or masters. A thorough understanding of the technical basis of cases enables our lawyers to argue trial cases better, repackaging information from scientists and companies so it can be better understood by a lay jury or judge. Similarly beneficial is an understanding of the technical intricacies of an invention and ability to argue back and forth with the patent office in an appropriate way. Overall, Steptoe is comprised of vigorous advocates devoted to its clients and their objectives.

How does the United States' strong IP protection framework affect the dynamics between branded and generic drugs?

Going forward, brand companies will create more of a thicket of patents, which is what we see in the biologics space. Companies will file for patents around a number of processes and methods of use as well as the compounds themselves. This requires the generic company to invalidate a greater number of patents in order to enter the market or free themselves of patent litigation, also helping the brand company to get around IPRs, creating higher entry barriers for the opposing company.

On the generic side, a larger volume of invalidation-related filings will have to be pursued. It is almost malpractice not to pursue a post-grant proceeding at this point, because the rules are somewhat favorable towards those trying to invalidate the patent. It makes sense for these companies to go for post-grant proceedings in conjunction with whatever the district court litigation is. With concurrent strategies, certain invalidity arguments can be pursued in Federal Courts while others can be pursued before the Patent Trials and Appeals Board.

As patents continue to be challenged more and more aggressively and brand companies strengthen their patent positions, how could the validity of these patents be affected?

Patentability, 'Section 101', is very important in the biologics space. These arguments, which say that even the patenting of a particular subject matter is not allowed, have appeared increasingly in the last few years in life sciences, especially in the biologics space. The test for patentability is firstly whether the claim is directed at something that is not allowed to be patented. In biologics, this would be a natural phenomenon or something that is naturally occurring. Pure products of nature cannot be patented – something must be done to it or it must be changed in some way. Examples of patentable subject matter includes novel processes, new compounds or novel antibodies, or an alteration of a naturally-occurring substance. The law is evolving in this area and increasing in clarity..

In patent invalidation strategies, this might be brought up very early on in the case, even in the pleading stage, summary judgement or at trial. In the pleading stage, it can be argued that the patent by law should not have been granted to win the case. We are seeing these 101 arguments being made at earlier stages of cases, in addition to later on in the case.

Have there been any major developments in biosimilars guidelines?

Some of the biosimilars guidelines have become more finalized. Interchangeability guidelines continue to become more developed, providing greater incentive to develop interchangeable biosimilars as opposed to just biosimilars. Unlike a non-interchangeable biosimilar, an interchangeable biosimilar can be auto-substituted. As those guidelines develop, the exact tests needed to satisfy interchangeability will be continue to crystallize.

What will be the next efforts in bolstering in-house capabilities at the firm?

While we will always do the small molecule work, we are very focused on biologics for the future, whether in antibody therapy, DNA-related technologies or gene technologies. There have only been a handful of biologics trials so far, and Steptoe is one of the few firms to have argued one of these big antibody trials. We continue to expand our team and continue to take on cutting-edge cases. We maintain a very focused support base between our attorneys who can understand the science as well as act as effective litigators and counselors. ■