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Nanotech Combination Products Challenge Classic Paradigms

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As the field of nanotechnology advances, the classical distinctions between what the FDA considers a "drug," "device," or "biologic" begin to blend together. Envision, for example, a molecular machine programmed to seek and destroy cancer cells. These machines would combine into one therapeutic product – a nanoscale device for delivering a payload of drugs, together with a biologic component that self-assembles into a protective capsule around the delivery site, focusing the drugs on the cancer site within this capsule.

Just as a nanotech combination product unites these three physical components – drug, device, biologic – the regulatory, intellectual property, and business law issues are intertwined as well. To succeed in the marketplace, innovators developing combination products must be armed with an integrated legal strategy.

REGULATORY ISSUES

All products submitted for FDA approval are first assigned to a particular Center that will have primary jurisdiction for regulating the product. Drugs, devices and biologics each have their own Center. Combination products are assigned to a Center based on their "primary mode of action." Making this determination, however, is often difficult. More practically, there are large variations between the three Centers, in terms of time and money required to obtain FDA approval. Therefore, a combination product's designation to a particular Center could have a big impact on a company's ability to attract financing and reach its scheduled milestones.

INTELLECTUAL PROPERTY ISSUES

A patent application needs to be filed with the Patent and Trademark Office before applying for FDA approval. Applicants must be careful, however, when making statements to the PTO about the product's therapeutic effect, lest the FDA later use those statements when assigning the product to a particular Center. Combination products also present the problem of obtaining patents needed to broadly exclude competitors. If a patent only covers a device combined with a specific biologic, then a competitor might avoid infringement by switching to a different biologic.

In addition to excluding competitors, developers of combination products must also worry about infringing other parties' patents. The likelihood of infringement increases with each additional component of the combination product. For instance,

a manufacturer might need to negotiate a separate license agreement with a large pharmaceutical company for the drug component; a micro-electro mechanical system company for the device component; and a biotech start-up for the biologic component.

BUSINESS ISSUES

The success of a combination product will ultimately hinge on strategic choices regarding its distribution and reimbursement. Do you sell the drug-device-biologic product to a large pharmaceutical company that specializes in pharmaceutical drugs; to a medical device company; or to a company that makes both? Will doctors receive the completed product, or will they insert the drug into the delivery device? Because nanotechnology is inherently cross-disciplinary, the physicians who administer nanotech combination products might need to be trained across several disciplines.

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Nano-enabled combination products will inevitably change the way we diagnose and treat patients, ultimately allowing us to seek and destroy diseases within the body. To successfully reach the marketplace, the developers of combination products must consider the overlapping regulatory, IP, and business issues. ●

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