

## Biotechnology and Life Sciences

We represent growing and emerging companies in the life sciences, which include biological and genetic sciences. Our life science expertise includes three basic areas: diagnostics, therapeutics, and biologics. In each of these areas, the assistance of patent counsel at an early stage of development is essential. Protection of trade secrets, intellectual property protection and freedom to operate are essential elements of a successful development strategy due to the high costs and regulatory approval processes of:

### **D<sub>x</sub>**

Diagnostics (D<sub>x</sub>) is a rapidly growing field and includes tests for diagnosing disease, co-developing drug diagnostics for determining efficacy and avoiding severe side effects, and genetic testing of individuals or individual diseases for prescribing therapies and preventing disease. These areas include traditional and cutting edge applications for diagnostics requiring unparalleled expertise in both the life sciences and intellectual property.

### **R<sub>x</sub>**

Therapeutics (R<sub>x</sub>) include drugs, medical devices and therapeutic procedures. Therapeutics are useful for repairing, treating or preventing disease. However, in the early stages of research, a company might not know what actual use a specific therapeutic might have. Issues of patentability of certain therapies both in the United States and elsewhere in the world are common. Claim drafting expertise is essential. We help our clients develop an intellectual property and regulatory strategy for protecting exclusivity to the intellectual property developed by our clients developing therapeutics.

### **B<sub>x</sub>**

Genetic engineering of biologics (B<sub>x</sub>), nanocatalysts and biocatalysts have shown promising development. Early stage companies are finding sources of financing to enter into fields of increasing crop yields, alternative fuels and waste treatment and environmental remediation. Companies can expect to need one or more licenses for these technologies. We assist clients in developing regulatory compliance policies, an intellectual property portfolio and reducing exposure to the risk of patent infringement lawsuits. Research and development may be targeted based on both potential technical success and freedom to operate if R & D proves to be successful.

### **Regulatory Compliance**

Life science products, devices and therapies are heavily regulated by federal and state agencies. The Life Science practice provides regulatory review and advice for compliance with federal and Florida State laws for the manufacture and sale of nanotechnology, biotechnology, foods, drugs, pesticides, cosmetics and other regulated products and services, especially in the areas of nutritional, health and beauty products. Many companies are not fully aware of the need for regulatory approval in these areas. Compliance with labeling laws and prior approval for any use, sale or manufacture of any product making health related claims or any product relating to nanotechnology must be ascertained in order to avoid regulatory



#### **Practice Leader**

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noncompliance and civil liability, fines or criminal prosecution.