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Emerging Life Sciences Companies

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Chapter 36

Expanding to the United States: Issues for a Biotech Company to Consider in Preparing for a U.S. Market Entry

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EXPANDING TO THE UNITED STATES: ISSUES FOR A BIOTECH COMPANY TO CONSIDER IN PREPARING FOR U.S. MARKET ENTRY

When a foreign biotech company decides to expand its operation beyond its borders and into the United States, such a decision brings with it not only a number of opportunities but also a number of challenges (e.g., where to locate, from where to hire employees, how to navigate the different regulatory regimes). The following outline sets forth some of the issues and considerations that need to be made by a foreign company when preparing for market entry into the United States.

Preliminary Considerations

A. Check domestic legal and tax consequences of a U.S. market entry

B. Choice of location for office in the United States

   1. State incentives (e.g., tax breaks)

   2. State law (corporate, securities, insurance)

   3. Proximity to desired employee pool

Corporate Structure Considerations

A. Formation of U.S. subsidiary—consider what type of U.S. entity to establish (e.g., corporation, partnership, limited liability company) or whether to operate in the United States as a division

B. Acquisition of U.S. company for U.S. market entry

C. Contractual arrangements with existing U.S. companies (e.g., outsourcing ancillary services, co-development arrangements, distribution arrangements)

Financing Structure Considerations

A. Consider available state Economic Development Authorities (EDAs) and grant programs

B. U.S. entity debt financing

C. Asset-based or project debt financing

D. Venture Capital—private investment firms may provide capital for equity stake in U.S. entity

E. Issuance of securities on U.S. public market "foreign private issuers" requirements of the Securities Act and the Exchange Act

1. Register foreign company securities as ADRs

2. Register securities in U.S. subsidiary

3. SEC requirements

a. SEC rules and regulations

b. Registration requirements

c. Disclosure requirements

d. Ongoing reporting requirements

F. Exceptions to the registration requirements for certain private placements

G. Additional requirements may be posed by state securities laws (known as "blue sky" laws)

U.S. Entity Governance

A. Constitution of U.S. board of directors

1. Parent representatives

2. Management representatives

3. Outside investor representatives

4. Independent directors

B. Protective provisions

1. Parent

2. Outside investors

Statutory Legal Considerations for Foreign Company Doing Business in the United States

A. Compliance with the International Investment and Trade in Services Survey Act

B. Compliance with the Foreign Agents Registration Act

C. Compliance with the Currency and Foreign Transactions Reporting Act

D. Foreign-owned entities face special rules when seeking contracts from U.S. governmental entities, such as the Buy American Act, and certain industry-specific limitations

E. Real estate ownership restrictions

1. Primarily state law, which may pose some restrictions on ownership by a foreign company
2. Federal law
    a. Compliance with the Trading with the Enemy Act
    b. Compliance with the International Emergency Economic Powers Act
    c. Compliance with the Foreign Investment in Real Property Tax Act

Labor and Employment Considerations

A. Taxation for foreign employees working in the United States

B. Executive compensation for U.S. management

C. Compliance with U.S. federal, state, and municipal employment laws and labor standards—need for employee handbook

D. Employee benefit plans need to comply with U.S. Employee Retirement Income Security Act

E. Compliance with the Occupational Safety and Health Act

F. Workers' compensation

G. Advance notice requirements prior to termination (e.g., Worker Adjustment and Retraining Notification Act)

H. Compliance with immigration law

Tax Considerations

A. Taxation of foreign companies doing business in the United States depends on many factors, such as tax treaties, U.S. entity structure, federal and state tax laws, as well as domestic tax laws, and thus requires careful structuring to find the best possible solution

IP Considerations

A. IP contributed vs. licensed from parent

B. Valuation of IP contribution

C. Terms of contribution (all equity vs. royalty—consider both tax and economic implications)

D. Identification of IP that needs to be protected in the United States

E. Are there any patentable inventions not yet patented in the United States? If so, patent applications must be prepared and filed with the U.S. Patent and Trademark Office.

F. Confirm freedom to operate

G. Which trade and service marks will be in use in the United States? Conduct a mark search to identify preexisting marks/potential conflicts. An application for federal registration of a mark may be filed with the PTO on the intent to use alone; however, it will not mature into a registration prior to actual use of the mark in the United States.

H. Copyrights: Unlike most other jurisdictions, the United States provides for the registration of copyrights with the U.S. Copyright Office. Such registration is not mandatory for copyright protection; it may, however, lend important advantages and benefits in potential copyright infringement suits.

I. Which trade secret protection laws are in effect in the target state? These laws may overlap with available patent protection.

J. Are there any license agreements in effect in the United States that grant someone else exclusive rights to use your IP (or parts of it)? Any conflicts need to be resolved before entering the market.

FDA Regulatory Considerations

A. Develop a clear regulatory pathway strategy

B. Is your product a "new drug" as defined by the Federal Food, Drug, and Cosmetic Act (FFDCA)? If so, you need to file a new drug application (NDA) prior to marketing it in the United States. If not, you may file an abbreviated new drug application (ANDA) after a certain exclusivity period and subject to noninfringement on the rights of the NDA holder/patent owner.

C. Under certain conditions, the U.S. Food and Drug Administration (FDA) will accept foreign clinical trials in support for an NDA. Do clinical trials so far conducted by your company meet those requirements?

D. Strict regulations apply to labeling, promotion, and advertisements. Prior to disclosing any information about your product, verify that you are not violating the FFDCA or any FDA regulations.

E. Filing requirements: Certain agreements between pioneer drug companies and ANDA applicants are subject to antitrust review by the Federal Trade Commission and the Department of Justice.

Pricing and Reimbursement Considerations

A. Private and government insurance reimbursement strategy

B. Price discrimination

C. Medicare/Medicaid coding and reimbursement

D. CMS/State coding

Global Marketing and Operations

A. Advertising

B. Promotion/labeling/sampling

C. Good manufacturing practices

D. Postmarket reporting

E. Recall strategy

Preparing for Collaboration or M&A Transaction

A. Joint development

B. Co-promotion and co-marketing

C. License agreement restrictions

D. Manufacture and supply arrangements

E. Contractual restrictions on assignment of any key contracts

Litigation Avoidance Strategy

A. Corporate conduct policy

B. Recordkeeping policy