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Emerging Life Sciences Companies

second edition

Chapter 27

Key Contract Provisions for License Agreements

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KEY CONTRACT PROVISIONS FOR LICENSE AGREEMENTS

The following outline sets forth contract provisions the parties should consider when negotiating and drafting license agreements.

License Grants to Purchaser

- A. IP covered
 - 1. Patents on certain starting materials/steps that may be used to make product
 - 2. Other patents relevant in the field
 - 3. Know-how and other unpatented technology
- B. Scope
 - 1. Only product
 - 2. Other analogs
 - 3. Next-generation products
 - 4. Field generally
 - 5. R&D
- C. Exclusivity
- D. Have made/sublicense rights
- E. Territorial limitations
- F. Freedom to operate grant (unblocking license)
- G. License-through of third-party rights
 - 1. Seller maintenance of third-party agreements
 - 2. Purchaser responsibility for any royalties/other amounts due to third parties
 - 3. Step-in rights of purchaser if third-party agreement is breached

License Grant Back to Seller

- A. IP covered
 - 1. Patents assigned to purchaser under asset purchase agreement
 - 2. Patent rights under license/settlement agreements assigned to purchaser
 - 3. Know-how and other unpatented technology
- B. Scope
 - 1. Only product
 - 2. Other analogs
 - 3. Next-generation products
 - 4. Field generally
 - 5. R&D
- C. Exclusivity
- D. Have made/sublicense rights
- E. Territorial limitations
- F. License-through of third-party rights
 - 1. Purchaser maintenance of third-party agreements
 - 2. Seller responsibility for any royalties/other amounts due to third parties
 - 3. Step-in rights of seller if third-party agreement is breached

Development Activities

- A. Coordination of development activities
- B. Sharing of filings, study results, data, and so forth
- C. Development committee
- D. Tie-breaking votes
- E. Limitations on pursuit of new indications
- F. Opt-out rights

Commercialization

- A. Consistency of training materials
- B. Consistency of labels, inserts, promotional materials, and so forth
- C. Use of trademarks and trademark rights

- D. Use of domain names
- E. Parallel imports
- F. Product pricing for different indications
- G. Exchange of sales information

Regulatory Matters

- A. Sharing of rights of reference to regulatory filings
- B. Sharing of regulatory correspondence and meeting minutes
- C. Participation in meetings with regulatory authorities
- D. Cooperation in responding to regulatory inspections and inquiries
- E. Handling of medical inquiries and complaints
- F. Sharing of information on adverse drug experiences, and so forth
- G. Sharing of other important product information
- H. Review/approval of joint promotional materials
- I. Handling of recalls and other corrective actions
- J. Recordkeeping and record retention
- K. Audit rights

Patent Matters

- A. Patent prosecution and maintenance
 - 1. By seller of patents licensed to purchaser
 - 2. By purchaser of patents licensed to seller
- B. Step-in rights
- C. Enforcement of patents against third parties
 - 1. In the territory
 - 2. Outside the territory
- D. Patent marking
- E. Patent term extensions
- F. Conflict with underlying license agreement for third-party patents

Trademarks and Copyrights

- A. License rights
 - 1. Trademarks
 - 2. Promotional materials, labels, and so forth
 - 3. Quality control standards
 - 4. Registrations and maintenance
 - 5. Enforcement
 - 6. Abandonment
 - 7. Competing marks
 - 8. Ownership/use of derivative works

Confidentiality and Publicity

- A. Mutual obligations
- B. Publications and public presentations of research/clinical trial results
- C. Existence and terms of agreement
- D. SEC filings
- E. Press releases

Representations and Warranties

- A. Basic corporate warranties
- B. IP
- C. Disclaimer of additional warranties

Indemnification and Limitations of Liability

- A. Breach of representations and warranties
- B. Infringement of third-party IP rights
 - 1. In the territory
 - 2. Outside the territory
- C. Product liability/personal injury claims associated with product
 - 1. In the territory
 - 2. Outside the territory
- D. Costs of recalls and other corrective actions
 - 1. In the territory
 - 2. Outside the territory

- E. Gross negligence or willful misconduct
- F. Procedures for third-party claims
- G. No liability for consequential and related damages

Term and Termination

- A. Term
- B. Termination
 - 1. For material breach
 - 2. For bankruptcy
 - 3. By mutual consent
 - 4. For convenience
- C. Sell-off/use of existing inventories
 - 1. Of product
 - 2. Of promotional materials, labels, and so forth
- D. Return/destruction of confidential information
- E. Cross-default of other agreements
- F. Survival
 - 1. All license rights
 - 2. Confidentiality
 - 3. Indemnification and limitations of liability

Miscellaneous

- A. Effect of change of control
 - 1. By seller
 - 2. By purchaser
- B. Assignment
 - 1. By seller
 - 2. By purchaser
- C. Bankruptcy protections
- D. Force majeure
- E. Insurance obligations
- F. Choice of law; dispute resolution