



## Chapter 27

# 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