Due Diligence

in

Licensing & Acquisitions

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NOVARTIS



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Michael Glynn is vice president, patents and trademarks for Novartis Corporation.

Prior to his current position, Mr. Glynn was vice president and counsel for Ciba's Corporate Patent Department. He is responsible for protecting the corporation's intellectual property, including obtaining and maintaining patents, trademarks and copyrights; evaluating the intellectual property rights of third parties; providing counsel on intellectual property litigation issues; and formulating corporate policies and procedures for effective patent, trademark, copyright and trade secret protection.

Prior to this appointment, Mr. Glynn held a variety of positions of increasing responsibility within the Corporate Patent and Legal departments. Before joining Ciba in 1974, he was a patent examiner for the U.S. Patent and Trademark Office. Mr. Glynn is a member of the American Bar Association, the Association of Corporate Patent Counsel, and the New York Patent, Trademark and Copyright Law Association.

Mr. Glynn received his B.S. in organic chemistry and his M.A. in education from Fairfield University; his M.S. in organic chemistry from the College of the Holy Cross; and his J.D. from the American University College of Law.

He and his wife live in Darien, Conn.

Seventh Advanced Licensing Institute - FPLC

EVALUATING LICENSING OPPORTUNITIES

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I. SUBJECT MATTER

A. The Res or Field

- compounds (active agents, intermediates, metabolites, etc.)
- formulations or devices
- processes of manufacture
- methods of use, treatments, etc.

B. Mode of Protection

- patents
- know-how
- patent applications
- biological materials
- regulatory exclusivity
- lead time
- trademarks

C. Scope and Strength of Protection

- broad or narrow
- strong or weak

II. THE BACKGROUND EVALUATION

A. Search for Patents and Literature

- prior and contemporaneous
- domestic and foreign
- dominating patents
- prior art
- patents, published applns. of the potential licensor

B. Order and Review of Patent File Wrappers (File Histories)

- claim analysis
  - scope and strength
  - U.S. and foreign

C. Title Search

- chain of title
- security interests
- prior licenses

D. Review of Publicly Available Records

- investor analyses
- 10K, 10Q reports

E. Litigation Check

F. Antitrust Analysis

G. Formulate Initial Assessment

- follow-up search
- prepare due diligence checklist

III. DUE DILIGENCE PROCESS

A. Secrecy Agreement

- enable potential licensee to review/assess Res
  - restrictions on use of proprietary information received
  - restrictions on who can have access to proprietary information
  - return or destroy proprietary info (except for archival copy) if no deal is reached

B. Due Diligence Checklist

- patents/patent application files
  - compounds
  - formulations
  - processes
  - methods of use
- info of potential licensor
  - 3rd party blocking or dominating patents or applications
  - potential interferences
  - prior agreements, oppositions
  - third party assertions or rights

- security interests
- govt. or other third party funding or research
- obligations to assign
- litigation or threats of litigation with third parties
- for biologicals, e.g. cell lines, chain of title assurances

C. Review, Analysis of Due Diligence Information

- compare with background evaluation
- identify discrepancies

- evaluate for further areas of inquiry
  - addl. searches
  - addl. requests for info. from the potential licensor

IV. THE LICENSE AGREEMENT

(Due Diligence Driving Factors in Clause Construction)

A. Representations and Warranties

- Clear Title
  - Identify Impediments
- Known Exposure Issues
  - Litigation Potential (Offensive and Defensive)
  - Interference Potential
- Duties to Third Parties
  - Pre-Existing Licenses
  - Third Party Funding

B. The Grant Clause

- scope of the Res
  - field restrictions
  - territorial restrictions
  - sublicensing rights
  - toll mfg. rights
  - assignability
  - bankruptcy
  - post expiration
  - improvements
  - grant back
  - exclusivity

- prior agreements
  - third party licenses
  - govt. funded research

C. Monetary Considerations
- milestone payments
- minimum payments
  - in place of "best efforts"

- royalty payments
  - patents
  - know-how
  - patent applications
  - trademarks
  - other
    - regulatory exclusivity
    - lead time
  - monetary conversion

D. Litigation Issues

- product liability
- infringement of third party rights
  - need for unblocking license

- infringement of licensor's patent rights
  - control/conduct litigation
  - damage issues

E. Expiration/Termination Issues
- Brulotte issue (post-patent royalty)
- know-how
- trademark
- cell line ownership
  - bailment issues