



Leveraging Intellectual Property for Biofuel Innovators

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Leverage Your IP

- 75% of all deal values are made up of intangible assets (Price Waterhouse Coopers).
- In 2005 80% of the market value of the S&P 500 resided in its intangible assets compared with only 17% in 1975 (CPA).
- “In the current economic climate, technology, innovation and creativity are critical in creating opportunities for economic renewal and addressing pressing global issues such as climate change.”
(Australian Director General of WIPO)

Leverage Your IP

- With concerns about oil prices and energy independence, investment in clean technologies such as biofuels has risen dramatically (e.g. ARRA).
- Innovator companies have two major obstacles to their ultimate success:
 - Create technologies that are both functionally and economically feasible.
 - Navigating the vast body of relevant technology patents that have issued or are pending.

Leverage Your IP

- Goals are to maximize the creation of new valuable intellectual assets and improve market competitiveness.
- Develop IP strategy consistent with business goals:
 - Internal Focus:
 - Identify sources of existing/potential IP
 - Protect intellectual assets offensively and defensively (*e.g.*, patents, trade secrets)
 - External Focus:
 - Freedom-to-operate issues

Internal Focus: Conduct an IP Audit

- Identify existing IP and potential sources of future IP:
 - Assists in developing/refining IP strategy for company's business goals
 - Strategy depends on biofuel company's products, services, current and future revenue goals
 - Confirm core technology is protected
 - Identify IP gaps
 - Re-asses IP periodically
 - Determine which IP is no longer worth pursuing/maintaining (e.g. foreign markets)

Potential Sources of IP

- Business methods
- Machines (e.g. reactors, equipment)
- Test data (even negative results)
- Customer lists
- Industrial processes (e.g. methods of hydrolyzing cellulosic material, methods of fermenting, optimized process conditions)
- Modified biological organisms (e.g. bacteria, yeast, algae)
- New use of known process or composition
- Improvements to any of the above (need not be revolutionary, can be evolutionary)
 - But see *KSR v. Teleflex*, 550 U.S. (2007).

Patent Fundamentals

- Right of patent owner to exclude others from
 - Making
 - Using
 - Selling or offering for sale in the U.S. or
 - Importing into the U.S.
 - a patented invention (determined by claims)
- For a period of 20 years from the filing date
- U.S. Patent Office accords "special" status (expedited prosecution) to patent applications for inventions which materially contribute to (a) the discovery or development of energy resources, or (b) the more efficient utilization and conservation of energy resources.
 - Consider if need quick issuance (e.g. funding or enforcement)

Business Advantages of Patent Protection

- Commercial advantage over competitors
 - Establish proprietary leadership position in biofuel market
 - Force competitors to spend money to design around or license your technology
 - Blocking patents (broad coverage or non-core technology)
- Financial rewards for bringing innovative and useful products into the marketplace:
 - Directly by making or selling the invention
 - Indirectly by licensing others to make or sell the invention
 - Creates shareholder value
 - Recoup dollars spent on R&D
- Validates the technology
- Stops unfair competition by those who compete by imitation
- Provides valuable trading assets to help assure freedom to operate (e.g. cross-license)

Requirements for Patentability

- A patent is granted to the first inventor (U.S. is still first-to-invent) of:
 - Novel
 - Useful; and
 - Nonobvious
- Process (method), machine, article of manufacture or composition of matter (e.g. chemical compound) and new and useful improvements thereof.

What is Patentable?

- “Anything under the sun that is made by man.”
 - *Diamond v. Chakrabarty*, 47 U.S. 303 (1980)
- Chemical compositions, mixtures of ingredients, formulations
- New uses of processes, compositions, e.g. use of known microbial enzyme in industrial ethanol fermentation process
- Modified biological organisms, e.g., bacteria, algae and yeast
- Modified plants, e.g., sugarcane, corn, switchgrass
- Industrial or laboratory processes, e.g. methods of pre-treatment
- “Isolated” or “purified” DNA, proteins and microorganisms

Utility Patents - When to Patent?

- In U.S., there is a one-year grace period to file which begins from the earliest:
 - Printed publication (e.g., publishing a paper or disseminating over the internet)
 - Sale (selling a product of that embodies the invention)
 - Offer for Sale or
 - Public Use (putting the invention into public use)
 - Which discusses or embodies the invention
- Most other countries require absolute novelty and offer no grace period (e.g. Japan).
- If world-wide patent protection is sought, file before any publication, sale, offer for sale or public use (e.g. poster abstracts, seminar presentations).
- Keep materials confidential (educate employees) until ready to file.
- Obtain CDA before disclosing to potential partner.

Trade Secrets

- A Trade Secret is something that is not generally known to the public that gives the possessor of the information a competitive edge or market advantage.
 - Value – economic advantage
 - Secret – capable of being kept secret (reverse engineer?)
- Perpetual protection (as long as secrecy is maintained)
 - Have a consistent policy in place (e.g. mark “confidential”, limit access)
 - Educate employees about policy
- Unlike patents, trademarks and copyrights (federal-based IP), trade secret protection is governed by state law.
 - Every state recognizes some form of trade secret protection.

Trade Secrets

- Nearly all companies have secrets; many of these secrets are trade secrets.
- Trade secrets may include:
 - Product Designs
 - Test Results (including unsuccessful tests)
 - Material Formulas
 - Manufacturing Processes
 - Customer Lists
 - Supplier Lists
 - Merchandising Techniques
 - Purchasing Information
- Company needs to decide to seek either patent or trade secret protection early while still confidential (patents and trade-secrets are mutually exclusive).
 - Example – cell line/optimized culture media used as internal tool which would not be used commercially.

Business Advantages of Trade Secrets

- Protect valuable technical information that cannot be protected under other forms of IP (e.g. patents).
- Protect ideas that offer a competitive advantage, thereby enabling your company to get a head start on the competition
- Keep competitors from learning that a product or process is under development and discovering its functional or technical attributes
- Protect valuable business information such as marketing plans, cost and price information and customer lists
- Protect "negative know-how" - information learned during the course of R&D on what not to do or what does not work optimally
- Protect any other information that has some value and is not generally known by your competitors

Trade Secrets vs. Patents

- **Trade Secret**

- Term: as long as it remains secret
- Cost: cost of keeping the information secret
- Registration: no registration or application required; automatic
- Protection: protects against stealing and copying of proprietary, trade secret information
- Enforcement: must prove existence of trade secret
- Requirements: secrecy; commercial value, not generally known or easily ascertained

- **Patent**

- Term: 20 years from filing
- Cost: drafting costs; prosecution costs; maintenance costs
- Registration: application must be filed, examined and granted
- Protection: protects functionality, operation, structure, idea - even if independently created
- Enforcement: presumption of validity
- Requirements: utility; novelty; nonobvious; written description; enablement; best mode;

External Focus: Freedom-to-Operate (FTO) Issues

- Patentability \neq freedom to operate
 - Patent is only a grant of the right to exclude others from making, using, or selling the patented invention.
 - Patent does not give patent owner the affirmative right to do anything (even to make, use, sell own invention)
 - KEY: A company can receive a patent for its technology and still be blocked from practicing that technology by a broader (dominant) patent.
 - Later patent to expressing novel termite cellulases in yeast would be blocked by earlier patent directed to expressing any exogenous protein in yeast
- BUT – subordinate patent can still have value
 - If subordinate patent is directed to improvement in the technology that is considered essential or particularly advantageous (e.g. specific enzyme with increased cellulolytic activity)
- Valuable subordinate/improvement patent can be a tool to clear FTO (e.g., through cross-license)

Freedom-to-Operate Issues

- The commercial market for the biofuel industry has increased dramatically, as has the number of patents to production technologies.
- A thorough understanding of the patent landscape is essential:
 - FTO search should be done early and focus on what is claimed (claims are often much broader than disclosure)
 - Do not expend resources developing technology only to find out your company is blocked from commercializing core technology by a third party patent.
 - Potential investors and partners generally consider FTO as important as, or more important than, a dominant IP portfolio.
 - Know risks at outset to determine strategies to remove impediments (e.g., license, re-exam, design around).

Resources to Help with FTO

- Expired U.S. patents
 - Technology in expired patents is in the public domain.
- Foreign patents
 - Patent laws are territorial.
- Each of these help the biofuel innovator understand clearly what can be practiced without permission of others.

Strategies for Clearing FTO

- Noninfringement/Design Around Analysis
 - Determine whether claims actually cover contemplated commercialization activity
 - Consider alternatives that will avoid claims (i.e., “design around”)
 - Review prosecution history at USPTO (road map to design-around strategies)
- Invalidity Analysis
 - Consider whether claims are anticipated by or obvious over prior art
 - Consider whether claimed subject matter is adequately described and enabled
 - Consider whether there was any fraud in procuring the patent at the USPTO which would render patent unenforceable

Strategies for Clearing FTO

- Reexamination Process
 - Process by which a third party can request that the USPTO reexamine an issued patent.
 - Faster and less costly than litigation (similar to oppositions in Europe)
 - The requestor must show that there is a substantial new question of patentability.
 - Easier in view of *KSR*
 - >90% of re-exam requests are granted
 - If the request is granted, the patent is looked at without a “presumption of validity”.
 - Used to cancel or amend claims in the patent that are not patentable in view of the submitted prior art.
 - In >70% of the re-exams, the claims are canceled or amended

Strategies for Clearing FTO

- Licensing
 - Consider whether taking a license is desirable/possible
 - Particularly if noninfringement/design around/invalidity positions are uncertain
 - Removes uncertainty of litigation
 - License more likely to be granted where patent holder is not a competitor and does not plan to exploit technology in your intended field of use
 - BUT – must keep in mind royalty stacking problem (particularly in biofuel production space)
 - Allow for need of possible licenses in future

Types of Licensing Agreements

- Non-exclusive
- Exclusive
- Field of Use
- Hybrid (know-how and patent rights)
- Cross-license
- Equity

Pros and Cons of In-Licensing

- Advantages:
 - Allows for making/using/selling of own technology
 - Extends pool of resources
 - Expansion into new markets
 - Leverage others' manufacturing/production capabilities
 - Provides rights to improvements
 - Controls competition
 - Security from litigation
- Disadvantages:
 - May create competition (e.g. cross-license)
 - Reduces level of control
 - Adds potentially unsupportable expenses (royalties)
 - Undermines independence
 - Expenditure of resources to design around licensed patents

Financial Considerations

- Unlike the pharma industry (profit margin >20%) the biofuel industry has a low profit margin.
- Develop licensing strategies that will minimize out-of-pocket expenses:
 - Royalty caps / royalty stacking provisions
 - Single payment/paid-up
 - Sliding scale royalties
 - Milestone payments
 - Equity arrangements

Be IP Savvy

- Know what IP your company has and protect future IP offensively and defensively
- Know critical dates for protecting IP in the U.S. and abroad
- Understand the lost opportunity costs if IP is not protected
- Identify FTO issues early and develop clearing strategies



Thank you!
Questions?
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