



FEDERAL LABORATORY CONSORTIUM
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**USDA Agricultural
Research Service
Licensing Policies,
Practices, and
Outcomes**

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JUNE BLALOCK

- Coordinator, Technology Licensing Program, USDA Agricultural Research Service, Office of Technology Transfer
- Appointed by Secretary of Agriculture as member of Plant Variety Protection Advisory Board
- Member, the Expert Advisory Committee on intellectual property for the Consultative Group on International Agricultural Research
- Member, U.S.-India Joint Working Group on Agricultural Biotechnology
- Represents USDA in negotiations on International Treaty on Plant Genetic Resources for Food and Agriculture
- Member of LES, AUTM, and American Society for Microbiology
- Previously, Associate Director of Triangle Universities Licensing Consortium
- Taught microbiology at the university level



OVERVIEW

- ARS Mission and Agricultural Markets
- ARS Licensing Goals and Practices
- License Diligence Requirements and Licensee Compliance
- Licensing Outcomes



ARS DECISION-MAKING PRINCIPLES

- ARS conducts research to develop and *transfer* solutions to agricultural problems of high national priority.
⇒ *Licensing policies are mission driven.*
- Research programs are designed with stakeholder input, and outcomes are measured by positive impacts. ⇒ *ARS has a “market pull” orientation.*
- A variety of tools are available for partnering and technology transfer. ⇒ *Use the right tool for the job.*



MARKET REALITIES FOR AGRICULTURAL TECHNOLOGIES

- Commodity pricing (Profit margins are tight.)
- Multiple competing technologies for commodity and consumer products
- Manufacture of value-added products moving offshore
- Industry consolidation in high volume market segments
- Many niche market inventions
- Difficult to find qualified/committed licensees for new materials



WHAT DOES THIS HAVE TO DO WITH THE PRICE OF CORN IN CHICAGO?

Changes in commodity prices have effects on multiple market segments:

- Growers \Rightarrow processors \Rightarrow consumers
- Livestock producers \Rightarrow processors \Rightarrow consumers
- Ethanol producers \Rightarrow consumers
- Growers of other grains \Rightarrow processors \Rightarrow consumers
- Seed companies
- Producers of value-added products



ARS LICENSING GOALS

37 CFR 404.2

“It is the policy and objective of (this regulation) to use the patent system to promote the utilization of inventions arising from federally supported research or development.”



ARS LICENSING GOALS (Cont.)

37 CFR 404.2, paraphrased

A federally owned invention should be patented when a private sector partner is needed to achieve technology transfer

AND

that partner requires some scope of exclusivity to protect the capital investments needed to commercialize the invention.



ARS LICENSING GOALS (Cont.)

- Use the patent system to facilitate technology transfer
- Provide an incentive for investments by the private sector
- Support small business enterprises and entrepreneurs
- Support investments by U.S. businesses in international markets



SELECTED ARS LICENSING DATA FOR FY 2006

| | |
|---|---------------|
| ▪ Active patent licenses | 332 |
| ▪ Licenses generating earned royalty income | 100 |
| ▪ Total license revenues | \$3.2 million |
| ▪ Total earned royalty income | \$2.3 million |
| ▪ Median earned royalty income | \$5,194 |
| ▪ Maximum earned royalty income | \$230,296 |



ARS LICENSING PRACTICES

- Patenting decisions are based on technology transfer requirements.
- No licenses are required for research-only use of ARS inventions.
- Most licenses are exclusive or partially exclusive.
- Exclusive licenses for plant varieties reserve the right to make the licensed varieties available to others for research and breeding.



ARS LICENSING PRACTICES (Cont.)

Applying for a License

- Detailed instructions are available on the ARS Partnering web page.
- This is an interactive process. Licensing Program staff are available to answer questions throughout the application process.
- This is NOT a bidding process. The first application received for an invention is evaluated on its merits.



ARS LICENSING PRACTICES (Cont.)

License Application Review

- Applications are evaluated based upon the requirements of 37 CFR 404.8.
- If the license application is complete and sufficient and the applicant requests an exclusive license, then a Federal Register Notice is published. Most objections received are because the objecting party also wants a license. The licenses granted may be co-exclusive, exclusive by field of use, or nonexclusive.



ARS LICENSING PRACTICES (Cont.)

License Negotiations

- This is a team effort. Successful negotiations require technical, legal, and business expertise.
- Inventor input is essential for technical discussions with license applicants.
- Inventor participation in business negotiations creates the appearance of a conflict of interest.
- The market approach is used for valuation.
- The applicant receives a negotiable offer.



LICENSE DILIGENCE REQUIREMENTS

- Diligence begins with license application review.
 - *Do we understand the applicant's plan?*
 - *Is there a clear timeline with milestones?*
 - *Does the applicant have access to all of the necessary resources to carry out the plan?*
- The license agreement requires the licensee to carry out the submitted plan and to report annually on progress, with reference to the plan.



ADDITIONAL DILIGENCE REQUIREMENTS

- Target date for offering licensed products or services for sale
- Intermediate milestone dates for making submissions to regulatory agencies
- Escalating annual license maintenance fees
- Milestone payments
- Requirement to keep licensed products or services reasonably available to the public



SPECIAL DILIGENCE REQUIREMENTS

- Some applicants may need to find a manufacturing, marketing, financial or technical partner to gain access to resources needed to carry out the commercialization plan.
- Contingency language may be included in the license agreement.
- Most commonly, this occurs when applicants are entrepreneurs or startup businesses looking for investors.



SPECIAL DILIGENCE REQUIREMENTS (Cont.)

Sample Language

“LICENSEE shall enter into an agreement with one or more Financial Partners to secure initial funding sufficient to fulfill the milestones identified in LICENSEE’s development and marketing plan. At a minimum, LICENSEE shall secure an initial commitment of _____ Dollars (\$_____), in cash, in-kind contribution or a combination thereof, within eighteen (18) months of the Effective Date. This period may be extended for an additional six (6) months upon written request by LICENSEE. No further extensions shall be granted by USDA, except under extraordinary circumstances and by mutual agreement of the parties.”



SPECIAL DILIGENCE REQUIREMENTS (Cont.)

Sample Language (Cont.)

“Financial Partner shall mean any person, corporation, firm, partnership or other entity which agrees to provide capital for the development, scale-up, production, field and market trials of Licensed Products, in accordance with the development and marketing plan submitted to USDA by LICENSEE with its license application.”



LICENSEE COMPLIANCE

- Licensee compliance is reviewed twice per year until the license expires or is terminated.
- License terms can be renegotiated if market conditions change.
- Most terminations are negotiated.
- All licenses provide the right for USDA to audit the licensee's records, at USDA expense.



OUTCOMES: BENEFITS TO INVENTORS

- Successful licenses document “impact” for RPES review.
- Inventors (collectively) are awarded the first \$2,000 of income received for a particular invention each calendar year, plus 25% of any additional income received that year.
- An individual inventor may be awarded no more than \$150,000 each calendar year for all inventions licensed.



OUTCOMES: BENEFITS TO LICENSEES

- The bottom line IS the bottom line.
 - New process reduces cost of production
 - Novel product replaces existing competing products
 - Improved product increases market share
 - New business is created
- The licensee is granted the right to enforce the patent rights, subject both to USDA review of the facts and to due diligence efforts to resolve the alleged infringement through negotiation.



OUTCOMES: BENEFITS TO SOCIETY

- Availability of new products and services
- Less expensive or improved products and services
- Creation or retention of local jobs
- Downstream impacts on other businesses providing supporting products or services and on the quality of life for consumers



IN CONCLUSION

“The path towards commercialization can be indirect and idiosyncratic.”

Dr. Paul Heisey, USDA, ERS

“Government Patenting and Technology Transfer”

<http://www.ers.usda.gov/Publications/ERR15/>

