SUPPORT FOR THE MANAGEMENT OF INTELLECTUAL PROPERTY WITHIN THE PIERCE'S DISEASE RESEARCH INITIATIVE AND RESEARCH COMMUNITY

Project Leader:
Alan B. Bennett
PIPRA
University of California
Davis, CA 95616
abbennett@ucdavis.edu

Collaborators:
Cecilia Chi-Ham
PIPRA
University of California
Davis, CA 95616
clchiham@ucdavis.edu

Sara Boettiger
PIPRA
University of California
Davis, CA 95616
sboettiger@ucdavis.edu

Rohan V. Patel
PIPRA
University of California
Davis, CA 95616
ropatel@ucdavis.edu

Reporting Period: The results reported here are from work conducted September 2006 to September 2007.

ABSTRACT
The Public Intellectual Property Resource for Agriculture (PIPRA) and the California Department of Food and Agriculture Pierce's Disease and Glassy-winged Sharpshooter Board (Board) began collaborations in 2005 with the goal of instituting an intellectual property (IP) management strategy inline with the Pierce's disease (PD) research consortium's mission. Within the last year, a number of information resources have been developed by PIPRA specifically tailored for the PD research community. These resources include a publicly accessible, live and comprehensive database of all PD related IP and scientific literature, an analysis of the IP and scientific literature surrounding PD research, and an IP landscape surrounding a promising PD specific technology. Collectively, these resources provide scientists an integrated view of the technical and legal aspects involved in their projects.

INTRODUCTION
PIPRA is a not-for-profit research organization hosted by the University of California, Davis. PIPRA currently represents 47 public sector organizations from thirteen different countries and its mission is to enable access to agricultural IP. PIPRA offers a range of services to address legal issues that arise during research and deployment of bio-technologies. PIPRA and the California Department of Food and Agriculture Pierce's Disease/Glassy-winged Sharpshooter Board (PD/GWSS Board) began collaboration in 2005 to address IP issues surrounding PD research and development. California's wine industry is a $51.8 billion industry in terms of total economic impact on the State of California, and a $125.3 billion industry in terms of total economic impact on the national economy [1]. Therefore, the threat PD poses to California's wine industry requires foresight to seek and secure commercial deployment of feasible technologies resulting from funded research. In terms of IP, the Board would like to ensure that technologies with the potential to control PD could be promptly deployed without becoming tangled in a legal web of licenses, rights, and lawsuits.

Technologies resulting from research funded by issue-focused consortia and conducted at multiple institutions, as in the case of the PD consortium, can face three basic IP problems during research and development. First, the researchers themselves may not be aware of their obligations or opportunities with regard to patenting research discoveries. Second, once patented, new discoveries are rightfully the property of the funded research institution or university, which may have internal policies regarding licensing that may be inconsistent with the objectives of the consortia. And third, the new technologies may be blocked by already existing patented technologies. These kinds of IP issues are not uncommon in industry consortia. They are, however, often resolved up front by contractual relationships or formal joint ventures that take into account the participants' IP management strategy. Consortia of universities and other public research entities, however, typically do not have well developed IP management strategies in place, in part due to the fact that public sector researchers often pay little heed to the proprietary nature of their research inputs and outputs.

PIPRA recognizes that an IP management strategy for the PD consortium needs to take a multilateral approach toward maximizing the effectiveness of the consortium's intellectual assets. Rather than focusing solely on IP protection, IP management for the PD consortia should also set milestones for technology development, assess marketing opportunities, and seek a better negotiating position during IP exchange. PIPRA seeks to aid the Board in coordinating IP to allow for access and protection, both of which are essential to the productivity of research across multiple institutions, while creating opportunities and incentives for further commercial development.

The first step toward effective IP management is the availability of information resources specifically tailored to Board funded PD researchers. Such resources provide scientists with technical and legal information critical for the deployment of marketable products with maximum security over IP rights. This report discusses the information resources specific to the PD research consortium developed by PIPRA.

Details of objectives set out regarding maintenance of the PD/GWSS-PIPRA IP and Literature databases, as well as an IP and technical audit of a PD related technology will be included. Additionally, ongoing and future objectives will be discussed in detail.

OBJECTIVES

1. Maintenance of the PD/GWSS-PIPRA IP and Literature databases.
2. Development of an annual impact statement of sponsorship based on IP and publication indicators.
3. Conduct an IP and technical audit of a commercially promising PD related technology.

RESULTS

Objective 1: Maintenance of the PD/GWSS-PIPRA IP and Literature databases

The PD/GWSS-PIPRA Database currently contains over 6,000 IP records and over 2,500 scientific publications. This electronic library of IP and scientific publications has been updated on a quarterly basis to include the most recent IP disclosures, science publications, and licensing information available to PIPRA.

New additions made to the database include the conference proceedings from the 2006 Pierce's Disease Research Symposium. This update was unique in that PIPRA employed a different method to extract information from the published symposium proceedings. This new method allowed PIPRA to capture additional information which was not displayed in the 2005 version of the database, such as the focus area in which the proceeding appeared in, funding acknowledgements, and reference citations. This sort of information is valuable to both the CDFA PD/GWSS board and PIPRA because it allows for determining metrics which can then be used in the broad context of an impact statement. This improved method of data extraction was also used on all previous symposium proceedings, thus replacing all of PIPRA's old symposium records with new and more thorough records.

Maintenance and data updates of the PD/GWSS-PIPRA Database will continue on a quarterly basis. Furthermore, PIPRA anticipates making alterations to the current database interface so that it can clearly display the newly captured information.

Objective 2: Development of an annual impact statement of sponsorship based on IP and publication indicators

In 2003 a National Academy of the Sciences panel, reviewed the research conducted by the PD/GWSS research community. A report of this review was published in 2004 and made some suggestions as to the direction PD research should take. Since the publication of this report, no internal or external assessment was conducted to follow up on the progress of PD research. PIPRA suggested conducting one such assessment in the current service year by interpreting research outputs as indicators of PD research impact and progress. Typically, impact statements aim to answer two questions, what was/is the issue and what has been done to address it. While in the process of developing this impact assessment, PIPRA became aware of an independent external assessment (Research Scientific Advisory Panel [RSAP]), headed by Dr. Nancy Irelan, to evaluate progress of CDFA PD/GWSS Board sponsored research activities. Because the PIPRA impact statement and RSAP assessment have converging goals, collaboration between both groups was setup to design and execute a more thorough assessment of all agencies funding PD/GWSS research activities.

Assignment of tasks was divided into two parts. Nancy Irelan was responsible for recruiting the members of RSAP as well as recruiting the cooperation of program administrators and individual researchers to participate in this assessment. PIPRA was responsible for 1) collecting funding and scientific information on every PD/GWSS project sponsored by CDFA, USDA-APHIS, USDA-ARS, and the UC PD program, and 2) presenting this material in a concise two page summary format for RSAP members to review. Information necessary for this assessment were collected from multiple sources. Fundamental information, which is inclusive of project names, associated researchers, funding amounts and years, were provided to PIPRA by the administrators of each funding agency. This information was then used for querying bibliographic information on scientific publications and patents which seemed directly related to funded research. PIPRA searched for scientific publications and patents across multiple, large-scale databases available online, namely: ISI Web-of-Science, PubMed, PD/GWSS-PIPRA Database, and Delphion Patent Database.

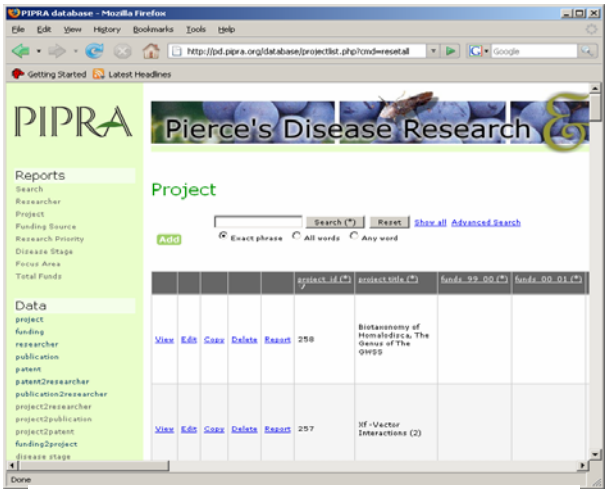

Figure 1. PD/GWSS-PIPRA Database.

A principal function of this database is to allow funding agencies to track the progress of research as a result of their funding. Another function is to allow researchers to update their peers on progress of research conducted, as well as to research duplication. Within this database, researchers may view all of the past and current PD projects, including the project objectives, publications, patents and related research projects. Researchers can also directly review and modify entries in the database related to their projects and other biographical information. This increases the efficiency and accuracy of updating the database.

Objective 3: Conduct an IP and technical audit of a commercially promising PD related technology
PIPRA conducted an IP audit pertaining to a promising PD technology, funded by the CDFA PD/GWSS Board. This audit consisted of a thorough IP landscape and prior art analysis along with an analysis of all contractual agreements affecting research and development of the target technology.

After a solution to PD has been developed, securing IP rights in relation to the invention will be vital. This means that all IP rights in the technology and the components, including the manufacturing process and method of application of the invention will need to be identified, in order to fully protect the technology. This should reduce the hurdles in the process of commercialization of the invention. The CDFA PD/GWSS Board along with RSAP recommended that PIPRA conduct analysis on a promising technology developed by Dr. Steven Lindow and colleagues.

Dr. Lindow and colleagues developed a novel genetic construct which can be used to disrupt extracellular bacterial signaling, preventing *Xylella fastidiosa* from effectively proliferating within its host. A patent application for the technology had been filed on behalf of Dr. Lindow by UC Berkeley. At the time this report was being written, the patent application was still unpublished by the United States Patent and Trademark Office, thus no information regarding its prosecution status was available. Analysis of the IP surrounding Dr. Lindow's technology revealed an extensive list of biological components which may require licensing in order to commercialize the technology. Some of these biological components may be replaceable with functionally equivalent components that carry fewer IP restrictions. PIPRA can work with Dr. Lindow collaboratively to design a plant transformation vector that is technically and legally suitable for research and development of this agricultural biotechnology.

Attention should also be given to regulatory challenges Dr. Lindow's technology may face prior to commercialization. A consumer-friendly approach should be taken when introducing a "genetically modified grape" so to increase consumer acceptance. Dr. Lindow's technology may be better accepted by grape growers and consumers if the technology is contained to the rootstock rather than spread onto the whole plant. This will allow the grapes resulting from plants with rootstock containment will be able to circumvent a "GM" label. It was recommended that the IP landscape around Dr. Lindow's technology be revisited prior to any commercialization so that infringement risks may be minimized.

CONCLUSIONS
The development of a successful IP management strategy is essential to creating a strong IP portfolio. With the advent of the information resources made available by PIPRA, scientists within the PD research community are now better capable to plan research projects with commercialization issues in mind. PIPRA also recognizes that these resources are only a part of a successful IP management strategy. Over the course of the next year, a number of objectives have been set out. These include maintenance of the PD IP and Impact database, streamlining PD research progress reporting, and an overall assessment of current IP policies and practices within the research community.

As previously noted, maintenance and updating of the PD IP and Impact databases will take place on a quarterly basis. At present, PIPRA is working to further improve the IP database through the use of a 'tier' system for the patent records included in this database. The database contains over 6000 patent records, all of varying relevancy to PD. At present, there is no way of sorting by relevancy to Pierce's disease. To make the database more useful, it has been proposed that a tiered system will be developed to address the issue of relevancy among the various patent records. In this way, any user of the database will be able to conduct an IP search and then sort the records by relevancy to PD. This work is ongoing at present.

Other ongoing and future work includes the work conducted on the objective of streamlining PD research reporting for research assessment. Currently, researchers must send in a report by certain deadlines. These reports must then be manually entered into the database. It has been proposed that an electronic research reporting system be developed to streamline the process of research reporting. To this end, a prototype demonstration of an electronic research reporting system has been made available online at: http://pd.pipra.org/database/cdfa-demo.html. This form allows for online submission of reports. When the form is filled out, it submits the information by email to PIPRA. This online form is composed of a number of fields, in which researchers are able to fill in the required information, as set out by the CDFA's guidelines. Additionally, there is a field included that allows researchers to upload PDF versions of their reports, which will then be submitted to PIPRA. There are many benefits to this type of system. First, it is simple. Second, the most important fields are filled in electronically, but the researcher submits a PDF and therefore has control of the formatting of the document. Finally, there is almost no maintenance required and the form can be easily hosted on any website, including CDFA's.

Another option would be to create a Microsoft Word document template. This template would include fields that could then be filled in individually by researchers. This option may prevent the loss of formatting and would allow data -- such as author names, abstracts, etc -- to be extracted automatically by software created by PIPRA. The final option would be to create a PDF document template. This has the same benefits as the MS Word template, but does not, in general, support including images and complicated markup. A decision will have to be reached regarding the form this electronic research

reporting system will take, and whether or not it is needed by the research community. Again, this work will be ongoing through the year.

These services will help implement an IP management strategy as the PD consortium prepares to advance the research and development of emerging industry solutions.

REFERENCES

MKF Research. (2007). MKF Research Report on Economic Impact of California Wine 2006**:** 2.

FUNDING AGENCIES

Funding for this project was provided by the CDFA Pierce's Disease and Glassy-winged Sharpshooter Board.