Workshop Report

Intellectual Property for the Applied Bioproducts and Crops Research Community

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VALGEN

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Summary

In January 2011, VALGEN hosted a workshop for investigators in Genome Canada's Applied Genomics Research in Bioproducts or Crops (ABC) projects to discuss three key areas in intellectual property that could impact their research projects: 1) patent landscaping 2) research collaborations and 3) data sharing. The group identified several tools and best practices for these three areas. As well, several lessons-learned and considerations for the future were brought forth. The tools, best practices and future considerations are summarized in the table below and elaborated on in the rest of this report.

	Patent landscaping	**Research Collaborations**	**Data Sharing**
Methods	• Government search engines (USPTO, EPO) *p.3* • International resources (WIPO PCT database, OECD Patent Statistics, Google Patent) *p.3* • Software (IPVisions' www.see-the-forest.com, Thomson Innovation) *p.3*	• Lambert Agreements – model research agreements *p.5* • IPXI- a financial exchange based on IP rights *p.5*	• Creative Commons licenses *p.8* • Uniform Biological Materials Transfer Agreement *p.8*
Models	• Bioactive Oils Program FTO analysis approach *p.3*	• BC Cancer Agency's collaborative practices *p.5* • Structural Genomics Consortium open-access *p.5* • AAFC MII program *p.6* • Public Private Partnerships in Pulse R&D *p.6*	• PIPRA *p.7* • International Knockout Mouse Consortium *p.8*
Lessons learned and future considerations.	• There are a variety of approaches and levels of detail that can be pursued for a patent landscape. • Scientists and patent experts should work closely. • A series of refinements is often required during the patent landscaping process. • Relationships between patents are extremely important. • Other assets and outputs beyond the patent should be considered.	• Trust needs to be built in all effective collaborations. • Explicit guidelines, agreements are necessary. • A research collaboration may involve other intellectual assets, beyond proprietary knowledge.	• What are the university technology transfer strategies that can increase the value of inventions stemming from academic research? • Patents as a metric of success could be a disincentive. • How do you encourage contributions back to the commons?

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VALGEN (Value Addition through Genomics and GE^3LS) investigates how scientific discoveries make their way from laboratory to the marketplace and also provides a networking mechanism to exchange methodologies, ideas and insights on the opportunities and challenges associated with agricultural and bioproducts genomics research and development. Over the past year VALGEN surveyed over 100 signatories to the Genome Canada funded ABC projects to understand the barriers and challenges that genomics researchers encounter. At a January 2010 alliance building workshop, both scientists and GE^3LS[1] researchers expressed an interest in continuing and elaborating on discussions on intellectual property. Specifically there was interest in evaluating patent landscape methods, potential research collaborations, and data sharing.

In January 2011, VALGEN facilitated a dialogue between among integrated GE3LS experts, researchers and VALGEN to present a variety of tools, models, case studies and best practices for the scientific community in the three areas of immediate interest to the ABC community.

Evaluating patent landscape methods

Patent landscapes are a way to visualize the intellectual property invested in a research program and efforts to commercialize research. The first session focused on landscaping because several of the ABC projects will be involved with developing an analysis of patents in their respective fields.

Dan Cahoy, Associate Professor of Business Law, Penn State University, began by noting that patent landscapes are different than a statistical analysis of patents. Statistical analyses are generally focused on the characteristics of individual patents and the assessment of predictive attributes. Landscapes, on the other hand, take into account the interactions and knowledge flows between the different patents and patent holders. They allow us to identify patents associated with a particular firm, industry, or region, as well as those in association with top inventors. Landscapes allow one to assess the technology environment by evaluating foundational patents versus improvement patents and noting the evolution over time. They can also enable an assessment of the portfolio value in relation to other patents. Importantly, statistical analysis is often integrated into landscaping, highlighting patents of a certain type in the overall technology environment.

Cahoy noted that different patent landscapes are designed depending upon the objective of the analysis. Cahoy described four levels of patent landscapes that range from simple patent counts to more

[1] GE^3LS stands for Genomics and its Ethical, Economic, Environmental, Legal and Social aspects.

sophisticated statistical and bibliometrics methods. At the simplest level, a patent count could tell you the number of patents in a particular field and provide a means of categorizing statistical data. This may be, for example, to compare innovation trends or changes in technology over time. A Level 2 analysis may provide an understanding of who owns the patents in particular field as well as related technologies. Both of these levels of analysis can be done for a low cost using resources such as national patent offices (USPTO, EPO), international resources such as WIPO's Patentscope® (http://www.wipo.int/pctdb/en/), OECD's patent statistics, and the recently enhanced Google Patents.

More sophisticated analyses look at complex relationships between patents. A Level 3 analysis looks at the relationship between complementary or overlapping technologies, often through a citation or semantic connection. Such analysis can be used to identify technology clusters or temporal clusters. Basic citation linkage information can be obtained from free patent office resources. Proprietary software can also provide useful graphic representations of such linking (and some, like IPVision, offer limited access for free at www.see-the-forest.com). The top level of analysis includes the value of patents as an aspect of the landscape, which in turn depends upon the scope and validity of patents as well as on the current and future markets. The broader the scope, the more likely it is that existing products and services will infringe the patent. In addition, other patents in the portfolio may influence the value of a particular patent right. Patent value can be assessed directly (e.g., from licensing income) if the information is available, but for large patent collections, indirect measurement through statistical proxies is more common. Given the need to incorporate complex statistical measures and data from several sources, this level of assessment is greatly assisted by proprietary software (such as Thomson Innovation). Based on this system of levels, Cahoy then recommended the following process be implemented in order to do a patent landscape. First, spend substantial effort to construct a pool of relevant patents. This should involve technology experts. Level 3 and 4 analysis can be used as a guide to find the most important patents. Finally conduct attorney-driven claim analysis in the hot spots.

Danielle Lewensohn, a VALGEN Research Associate at McGill University, expanded upon Cahoy's comments that there are many different approaches to conducting patent analyses. She pointed to the large variety of terms used in the literature to refer to such analyses including IP landscape, patent-statistics and patent-indicators that adds confusion to a systematic analysis of the field. This is further complicated by the lack of a uniform definition of patent landscaping. Examples of definitions discussed at the workshop include a time series analysis e.g. showing various trends over time, patent citation analysis, and International Patent Classification (IPC) analysis which classifies patents based on subject area. Other approaches to patent analysis include patent visualization, or claims analysis or looking at opposition and litigation suits. Lewensohn then provided several examples of patent analysis that were in the literature including 1) the quantity of related patents based on a key word list 2) technology-driven roadmapping 3) understanding how different firms relate to patent families 4) patent trends. Lewensohn concluded that patent landscapes need to balance standardized software systems with the subjectivity of experts and with the utility of the approach used.

Stuart Smyth, VALGEN Research Scientist at the University of Saskatchewan illustrated an approach to patent landscaping with the example of the Bioactive Oils Program (BOP). BOP, which started in 2007 to develop canola and flax seeds high in saturated fatty acids for use in the baking and health food supplements industries. Funded by AVAC Ltd., BOP includes three universities and the federal agency National Research Council's Plant Biotechnology Institute. With this case study, Smyth worked with his colleagues to identify domestic and international patents that could act as a barrier to BOP's research. This was found to be an evolving process that required progressive refinement, to distinguish significant keywords that captured both product and process-based patents and required input from both scientists and IP investigators working closely together. The timing of commencing the IP portion was also critical; the IP project began about one-year after commencement of the scientific portion, allowing for the scientific portion to be better established. It was also useful to identify key potential sales markets. Consideration of the timing of the patents was also essential. For example, IP that expires before the end of the scientific project could be largely ignored. The timeframe could even be extended a few years later than the end of the project due to the time required to take a product to market.

When barriers to freedom-to-operate were encountered there are a few approaches that may be employed. One approach, to ignore barriers, is subject to litigation. Another approach is to work around barriers by developing new methods, but this can be expensive and risky. Another strategy would involve steps like cross-licensing or other licensing arrangements. Other approaches involve the formation of public-private partnerships (P3s) or consortia. These both have the potential for strong relationship building and a long-term investment but P3s require common market goals. The final approach is to challenge patents in the legal system. For the BOP group where were two real market options: either to engage in licensing negotiations or to enter into P3 discussions. They found there to be one main industry patent holder and they were willing to license to BOP.

During the discussion it was also suggested that research organizations should note that patents do not represent all of the assets and outputs of research projects and collaborations. Training of personnel and the development of other vehicles of distribution such as databases (discussed further below) also hold a wide range of information and know-how.

In conclusion, all of the presenters in this session agreed that patent landscaping could involve a myriad of different approaches, each with their own advantages and applications as well as their own limitations. All three presenters discussed beginning patent landscapes with a broad search, involving scientists and perhaps using some of the software and tools that Cahoy brought forward. The patent landscape can then go through a series of refinements to identify critical areas, and meet the changing directions of the scientific research and commercialization efforts.

Intellectual property in research collaborations

Large-scale genomics research is accomplished in collaboration with other universities, industry and other organizations, each with their own IP policies and practices. Sharing information among various collaborators is essential to research and development in this field. The research collaboration ensures that knowledge is transferred to those that are developing new innovations. Nevertheless there are many challenges to sharing intellectual property. Session presenters discussed innovative strategies for research collaborations that overcome these challenges.

Sam Abraham, VP Strategic Relations for the BC Cancer Agency (BCCA) presented information on BCCA's collaborative practices. For the BCCA, IP protection is necessary. They seek patents not only to earn licensing revenues and attract research funding but also for defensive reasons as patenting ensures continued access and freedom to operate for themselves and their constituencies. To optimize research collaborations, the BCCA has developed guidelines for access to genomic and other 'omic information.' In general, they will agree to a contract with a defined, narrow scope of work and expected deliverables. The BCCA uses both exclusive and non-exclusive licensing. Non-exclusive licensing, where the license may be granted to more than one entity they found to be appropriate for early stage IP which they define as the basis for the subsequent development of separately patentable IP. Exclusive licensing is limited in scope to the development of specific drugs and only under agreement that does not permit broad patent claims. He concluded that for the BCCA, despite the need for some considerations, patenting is important to ensuring freedom to operate and encourages industry to work with the BCCA. It also ensures that they do not become reliant on one platform to result in a clinical outcome.

For innovation to occur, knowledge flow is essential. Richard Gold, Law Professor at McGill University began his presentation by noting that knowledge does not inherently move around. Some knowledge he said is sticky[2], and we need to overcome the stickiness of a technology to optimize information flow. Factors increasing the stickiness of knowledge include difficulties in identifying potential licenses and valuing the technologies, and the costs of transactions and negotiating an agreement. Gold provided three examples of tools and approaches that can be used to overcome technology stickiness.

The first example was the Lambert agreements, a set of model agreements for collaboration (http://www.ipo.gov.uk/whyuse/research/lambert/lambert-mrc.htm). By providing a standard set of agreements, the Lambert agreements overcome some of the challenges associated with the costs of developing a contract. It provides several model agreements ranging from a wide range of different types of organizations and multi-party arrangements.

The second example was IPXI (http://www.ipxi.com/), which is a financial exchange based on IP rights. This system overcomes two stickiness challenges: First, it allows more people to know of available licenses and access them. Secondly, it uses a built-in system to value IP, based on the merits of the invention, the commercial value and the quality of the patent coverage. IPXI further adds value, especially where knowledge is tacit by occasionally providing access to key personnel who hold the knowledge.

As a final, illustrative example, Gold discussed the structure of the Structural Genomics Consortium (SGC), a public private partnership with funding from governments, foundations and industry. The SGC is in the precompetitive arena, and identifies the 3-D structure of proteins. It is an open-access clearinghouse where neither the consortia nor its members seek patents over research outputs. Based

[2] Stickiness as a characteristic of a technology was first described by Eric von Hippel in 1994.

on the number of structures that have been contributed to public databases and the number and impact of scientific publications, the SGC has been successful. It is yet to be seen if this can work in downstream areas of life sciences for example, for clinical trials. More information on the SGC can be found at http://www.thesgc.org/about/open_access.php.

Peter Phillips, VALGEN Co-lead and Professor of Public Policy, University of Saskatchewan described the role of public private partnerships (P3) in life science research and development. He noted that P3s are intended as a long-term collaboration, and usually extend beyond a sharing of IP rights to an exchange of knowledge.

In a first case study, Phillips looked at private co-funding of public research, specifically Agriculture and Agri-Food Canada's program to leverage research dollars via the Matching Investment Initiative (MII), a program that began in 1998. At the time there was the concern that the use of industry dollars would reduce the research that became available in the public domain. To test this, Phillips looked at publications, citations and funding partners and found that this use of public-private partnership resulted in a citation rate that was double the global average, showing the P3 to be a very powerful partnership arrangement in augmenting scientific outputs.

Phillips also looked at the role of P3s in pulse crop research and development. Pulses describe a group of plants, such as chickpeas, lentils, and peas that provide a protein source. The privatization of plant breeding efforts combined with the relatively small acreage of these crops resulted in pulses becoming orphan crops with relatively little research investment from either private or public organizations. As a result, several P3s became established globally in this field. Phillips used a method called social network analysis, a statistical methodology which looks at linkages between institutions and provides information on the importance of an organization based on their location in the network, their role as a gatekeeper of information, and the power of their individual connections to look at interactions between the 248 organizations involved in pulse research globally. Forty-five P3s are involved in this global network and were found to be essential for linking local networks to global systems. In Canada, the P3 in pulse research is a collaboration between University of Saskatchewan's Crop Development Centre and the producer-driven Saskatchewan Pulse Growers (CDC-SPG). Removal of the CDC-SPG would result in complete isolation of the Canadian pulse research community.

From these examples, it appears that research collaborations between public and private sectors contribute immensely to agricultural research and development both in terms of developing scientific outputs and in innovation. Phillips' further research is examining behaviours in the establishment of P3s to determine how these collaborations can be established more easily.

In conclusion, the three speakers outlined several models of research collaboration that may be implemented in the research community to share knowledge, optimize resources, and further research programs. In some cases, proprietary knowledge needs to be considered, but the collaboration of other intellectual assets, and the furthering of research by linking to other systems and markets is also important.

Data sharing

Access to data is fundamental to genomics research, and a variety of approaches are available.

Greg Graff, Assistant Professor at Colorado State University, discussed PIPRA, a patent pool that could be adapted to genomics. PIPRA was created originally in 2004 with funding from the Rockefeller Foundation and the McKnight Foundation. It was a consortium of universities and public research institutes concerned that IP was a factor in preventing molecular biology from helping agriculture in developing countries and from contributing to the development of minor crops. Motivating the origins of PIPRA was three things. First a landscape analysis of Golden Rice revealed that over 40 US patents were involved in the development of one product that could be used in the developing would. Secondly an examination of the University of California's extensive patent portfolio analysis showed that the top 10 patents accounted for all of 75% of revenues and was related to specific cultivars such as strawberry and grapes used in wine-making. The other 170 patents represented only 25% of the total revenue and included a wide range of other traits. Finally an examination of the distribution of ownership in US patents over the previous 20 years (1982-2000) showed that the majority of ownership was held in the private sector. Since the IP in the universities portfolio was not licensing and the technologies were not reaching those in need, PIPRA was initially set up as a "patent clearinghouse model". This model was not found to be sustainable over time and PIPRA evolved to meet public sector IP needs. They now have three parallel lines of work: 1) publishing landscaping and freedom-to-operate analysis. This is accomplished with affiliated patent attorneys working *pro bono* that perform technology-specific FTO analysis along the R&D pipeline. 2) IP best practices and capacity building. 3) Building technology platforms and the patent pool. These include enabling technologies such as vectors and selectable markers.

In this model, PIPRA demonstrated the role of universities in becoming managers of research results to be utilized for the public good. Lessons that can be learned from PIPRA include the importance of ownership clarity and university technology transfer strategies that foster specialization and aggregation to increase the value of inventions stemming from academic research. Moreover, to facilitate knowledge transfer, a shift in the way academic research results are managed may be beneficial at certain universities and academic research settings.

Tania Bubela, Associate Professor, School of Public Health, University of Alberta discussed building a robust research commons. A research commons is as a shared and managed resource, for example a database or bio-repository where genomics data is deposited. It is a set of resources available to all researchers on terms that encourage efficiency, equitable use and sustainability. The value of a research commons is enhanced the more people that use it.

With this in mind, Bubela entitled her presentation "science's unobtanium." The term, popularized in the recent movie Avatar refers to something that is perfect but elusive - and the perfect model of data sharing seems to meet this definition. One of the barriers that Bubela noted was that data sharing was often mediated through technology transfer offices which also had commercialization focus, and patenting was seen as the key metric of success. As a result, this provided a disincentive for participation in a research commons.

There have been successful examples of data-sharing in the field of genomics. The International Knockout Mouse Consortium (IKMC) which includes NorCOMM (Canada), EUCOMM (Europe) and KOMP (US) is a public resource that provides public and private research communities with a source of knockout mice and embryonic stem cells. Participating organizations can still hold patents. Gene and DNA patents are generally held by the public sector, and cell lines and mice by the private sector. Nevertheless there are still some caveats. There is a risk that as the research moves towards clinical application phases, patents will negatively impact repositories and users. Also, the research community felt that material transfer agreements provided a disincentive to access and provide materials. Finally contributions back to the commons could be augmented as participants felt that researchers should be free to breed mice for research purposes and cross-breed them to produce new strains.

Open access requires a culture of collaboration and trust. Litigation is one way that trust can be destroyed. There could be other ways to enforce proper use, including through journals, funding agencies and other institutions. Rather than patents another metric might be materials and data publications or submission to a database as well as developing appropriate guidelines for attribution and citation of data in such a database. There are different considerations for producing data, publications and materials especially since databases are protected by copyright. Several examples of creative common licenses and waivers (CC0) are available at: http://wiki.creativecommons.org/Science. A standardized material transfer agreement is the Uniform Biological Materials Transfer Agreement. It is available at: http://www.nhlbi.nih.gov/resources/tt/docs/ubmta.pdf.

Overall, there was the feeling that the legacy of basic research patents under current laws and practices can hinder the establishment of public sector resources and that it is important to establish free open and ready access to data in the precompetitive space. Open data alone does not equate to equal capacity to use and it is important to build supportive and sustainable infrastructure. Data sharing should become part of the strategic direction for universities in the role as protectors of the public good. A shift in academia and industry practices is required, and impact on funding agencies and publications needs to be considered.

Conclusions

The presenters provided many tools and examples for the research community. In some cases the tools were directly applicable; for example several web-site tools for patent landscaping and sample MTAs, CCO, and Lambert agreements were provided. On another level, models and examples were provided that with some modifications can be adapted to the bioproducts and crops research communities. These included examples such as P3s and approaches to licensing and open access examples. Finally, the presenters and discussion provided some long-term strategies to consider such as changing incentive structures and the role of universities in protecting the public good.

Further Reading

Presenters at the IP workshop have kindly provided VALGEN with a copy of their presentations. They are available on our web-site at http://www.valgen.ca/ip-workshop/.

Policy Brief 18 March 2011: Performance of Canadian Technology Transfer Offices

Policy Brief 14 November 2010: Patent Infringement Remedies Have Limited Effects

Policy Brief 9 June 2010: Integrated GE^3LS within the Genome Canada ABC Competition

Policy Brief 7 April 2010: Intellectual Property Landscapes for Bioproducts and Crops

Policy Brief 3 December 2009: Intellectual property management & technology policy

Policy Brief 1 October 2009: Launch of an international research network