Intellectual Property Management in Livestock Veterinary Medicines for Developing Countries

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SYNOPSIS

The Global Alliance for Livestock Veterinary Medicines (GALVmed) is a nonprofit organization that makes livestock vaccines, diagnostics, and medicines accessible and affordable to the very poor. GALVmed coordinates research, development, and deployment (RD&D) among multiple partners, from identifying candidate technologies to manufacturing sustainable supplies of market-ready products. GALVmed uses a wide range of resources to ensure that IP supports innovation for the poor, such as due diligence for accessing upstream technologies, the implementation of IP strategies that work toward development goals, the use of IPRs as incentives to engage partners, and the negotiation of contracts that support the translation of research into products accessible to the poor. GALVmed's IP management system benefits its pro-poor mission by addressing broader issues that prevent innovations from becoming sustainable, market-ready products. Experience with public-private partnerships has taught GALVmed to leverage its interests while providing its partners with the opportunity to achieve their own internal mission.

CONTEXT

The Global Alliance for Livestock Veterinary Medicines (GALVmed, www.galvmed.org) is a nonprofit organization with a mission to make livestock vaccines, diagnostics, and medicines accessible and affordable to the millions for whom livestock is a lifeline. The Bill and Melinda Gates Foundation, the United Kingdom Department for International Development, and the European Commission are major sponsors of GALVmed's work.

The impact of livestock in addressing poverty continues to be underappreciated, particularly livestock's role as living assets for the very poor. Data on the impact of livestock diseases are limited, but four of the many major and unaddressed livestock diseases (East Coast fever, Rift Valley fever, Porcine cysticercosis, and Newcastle disease) cause estimated annual economic losses upwards of US$350 million. Losses on this scale affect the livelihoods of hundreds of millions of poor households in the developing world.

GALVmed currently works on nine disease-control technologies for those four livestock diseases. Many diseases afflicting livestock in developing countries are preventable and well understood from a research perspective. Until recently, however, the developing world has lacked the resources for moving the science out of the lab and into the field to prevent and contain livestock diseases. One reason for this impasse is that disease-preventing and disease-controlling technologies often emerge from R&D in advanced laboratories and are subject to one or more forms of IP protection.

For GALVmed to achieve its mission, the organization must constantly exercise (and review) its IP policies and IP management strategies. Through effective IP policies and management strategies, GALVmed can identify and circumvent IP risks early in the commercialization pathway, therefore avoiding potentially serious and costly downstream impediments to GALVmed projects.

GALVmed is unusual in that it operates across the entire commercialization pathway to make technological solutions accessible to the poor. GALVmed does not have in-house capacity for the research, development, and deployment (RD&D) of products. Instead, its role is to *facilitate* the entire RD&D process, from identifying candidate technologies to manufacturing sustainable supplies of market-ready products. Managing RD&D activities among multiple partners and under pro-poor obligations requires the organization to consider the use of IP strategically to ensure that upstream technologies do ultimately result in downstream products accessible to those who need them most.

By addressing a wide range of IP strategy issues, GALVmed has gained experience that has value for many

Box 6.35 Tailoring Intellectual Property Strategies for Public and Private Partners in Technology Deployment

The vaccine that GALVmed is currently deploying for East Coast fever has a commercial market, primarily among the Masai in East Africa, and potential for sustainable private sector production and distribution. Protection against East Coast fever adds significant value to Masai calves, and the Masai are willing to pay for the vaccine within a certain price range. With the help of the Public Intellectual Property Resource for Agriculture (PIPRA, www.pipra.org), GALVmed first approached the IP strategy for the vaccine by characterizing the opportunities and risks. The vaccine was nearly ready for the market and would not require substantial further development. PIPRA reviewed the IP in the technology. It determined that the technology and related know-how, although enormous in value, were in the public domain and had no associated IP rights.

The lack of formal IP meant that manufacturers would have less of an incentive to invest in producing the vaccine. GALVmed needed to explore other types of leverage, such as forward market commitments or other assurances of supply channels. Eventually GALVmed learned that deregulation of the vaccine in each country in East Africa was linked to an exclusive marketing authorization that offered some leverage. To create a commercialization strategy for sustainable delivery of the vaccine to East Africa, information on marketing authorizations needed to be integrated with information on the profit incentives of manufacturers and distributors as well as consideration of the transfer of know-how. In summary, even though IP did not play a role in the eventual commercialization strategy, formulation of an IP management strategy was critical to determine: (1) whether in-licensing was required and which partners might need to be engaged in the process due to IP ownership and (2) what incentives could be derived, either with IP or other levers, to ensure that partners also had incentives to comply with GALVmed's pro-poor obligations.

While commercialization of the East Coast fever vaccine involved private companies as partners in manufacturing and distribution, another vaccine in GALVmed's portfolio, the Porcine cysticercosis vaccine, involves virtually all public partners. In this case, GALVmed recognized that the lack of a private market for the Porcine cysticercosis vaccine (government procurement was anticipated) meant that incentives to engage manufacturers and distributors would need to be different. PIPRA conducted due diligence over relevant technologies and ascertained that, while formal IPRs existed in some countries, it was tangible property rights that would provide GALVmed with both challenges and opportunities in its development of a pro-poor commercialization strategy. GALVmed was then able to employ licensing language to create incentives for partners, whereby a selected partner would gain geographical exclusivity in developing, manufacturing, and distributing the vaccine. As was the case with the East Coast fever vaccine, developing an IP management strategy involved critical due diligence to determine GALVmed's risks and opportunities, and then careful consideration of how to use the available leverage to ensure that partners had incentives that aligned with GALVmed's obligations to deliver products to the very poor.

Source: Authors.

organizations that develop technology for the poor. GALVmed has made crucial IP decisions, observed their implications, and employed IP strategies suitable for both public and private partnerships (see box 6.35).

Through broad involvement with the RD&D process, GALVmed addresses IP and contractual challenges, including accessing and transferring proprietarily owned technologies, resolving the distribution of rights, and strategically using IP to promote deployment. The remainder of this profile focuses on the processes and resources GALVmed has employed to address IP issues, such as due diligence, strategy implementation, and conscious leveraging of IP, as well as some of the challenges involved (for example, negotiating contracts).

GALVMED'S INNOVATIVE APPROACH

As it has grown, GALVmed has developed a systematic approach that anticipates IP hurdles and mitigates IP risks that arise during RD&D (box 6.36). These IP management

Box 6.36 Internal Capacity Building for Strategic Intellectual Property Management

As GALVmed has expanded, its needs for managing IP have evolved. During its startup phase, to ensure that IP issues were addressed from the onset of projects with utmost diligence, GALVmed outsourced IP management issues to a group such as PIPRA, with a proven track record and the expertise for managing IP within agriculture. Five years after its founding, GALVmed now manages an ever-growing number of technologies in the RD&D pipeline. The related complex IP challenges demand timely attention and therefore in-house expertise. GALVmed's growing internal capacity for IP management has been achieved through three changes:

- ***Creating a new management role within the organization to deal with IP and agreements.*** This role provides for focused, consistent management of the drafting of time-sensitive agreements and delicate negotiations as well as critical accountability for IP management. Moreover, internal expertise allows for IP management strategies that fit the organization's risk tolerance, encompass organizational culture, and can more easily be adapted to changing information of the technical and socioeconomic realities of the RD&D pathway.
- ***Contracting the services of a local attorney from a top-tier law firm to provide weekly and as-needed support in drafting and negotiating complex legal agreements.*** A local attorney[a] provides the organization with an external opinion, identifies legal issues that could be missed internally, and provides insight on regional laws and regulations. The execution of contracts requires expertise in local law, and nonprofits often require legal opinions from local attorneys on risks such as exposure to liability. Most important, a local attorney is essentially local enough to meet individuals in the organization and understand the nuances of issues that would otherwise be missed through a phone call.
- ***Improving utilization of external IP expertise to address the resource gaps that almost always exist internally.*** External expertise, in the form of contracted services from organizations or individual consultants, can provide experience-based, impartial advice that would be difficult to gain otherwise. External expertise (in GALVmed's case, from PIPRA) has access to the knowledge and expensive toolsets that small nonprofits may struggle to purchase. These experts have access to a global network of attorneys that can provide regional legal advice that can be valuable, for example, when questions of law arise in countries where GALVmed's partners practice. Lastly, external experts have the latest specialized insight on IP. They are capable of breaking down technologies, conducting highly detailed assessments, acquiring legal insight, and converting a mass of information into one thorough, meaningful report that GALVmed's internal expert can then integrate into a larger commercialization strategy.

Source: Authors.
a. Andy Harris, associate at Maclay Murray & Spens LLP, Edinburgh.

measures are critical to GALVmed's ability to efficiently transform upstream disease-preventing technologies into safe, effective, and accessible downstream products.

The sections that follow provide more detail on GALVmed's four-stage, systematic approach to managing IP. The approach was designed to balance the organization's nonprofit, pro-poor mission with the need to integrate and address a variety of challenges arising throughout the commercialization pathway of the products GALVmed seeks to deliver to the poor.

Stage 1: Technology landscaping

GALVmed's initial step of conducting a technology landscape requires using IP and other sources of information to scout for preexisting and emerging technologies. Technical and scientific value of individual technologies are assessed as well as potential IP risks. In one instance, scientists at GALVmed learned of a number of technically promising, but proprietarily owned, vaccine stabilization technologies. Upon IP review, GALVmed learned of related ongoing

patent disputes. The uncertainty and risk associated with these disputes, and the potential impact these risks may have on downstream partners for technology development, were considered in conjunction with technical issues, and the risk was deemed unacceptable. The review of IP issues allowed GALVmed to avoid pursuing a technology that could have potentially led to delays or the expense of late-stage shifts in research strategy. Early identification of technologies that exhibit scientific merit and withstand IP review paves the path to a more resource-efficient commercialization process.

Stage 2: IP due diligence

As candidate technologies are identified from Stage 1, an IP due diligence process is used. This due diligence (or IP auditing) is a resource-intensive process involving in-depth research into the patent landscape surrounding each selected technology (for example, individual investigations of vectors, genes, promoters, markers, and signal sequences of a vaccine). When a patent is particularly important to GALVmed's commercialization strategy or when use of a technology is suspected to infringe existing patents, freedom-to-operate (FTO) assessments may be carried out with the help of attorneys. The information gained from IP due diligence allows GALVmed to identify potential partners, understand in-licensing obligations, and review potential opportunities for the use of IPRs in further development of the technology.

While some large companies employ internal IP legal expertise, it is usually more efficient for small companies and nonprofits to outsource this level of patent landscaping and analysis. For these analyses, GALVmed collaborates with PIPRA. In this stage, GALVmed also incorporates a review of issues of tangible property rights[1] (examining, for instance, material transfer agreements as well as IP licenses); existing claims to both tangible property and IP are mapped to understand the full implications for commercialization. Rights to ownership and the terms of use for technology providers, partners, and GALVmed must be clearly documented for any background (existing) and foreground (future) IP used or generated throughout RD&D. Finally, a review of rights and obligations of relevant existing legal agreements is also conducted at this stage.

The importance of due diligence for RD&D is often underestimated in agricultural development; as a consequence, organizations operate in an environment of uncertainty and risk. Sponsors who invest in organizations like GALVmed are incurring unnecessary risk if they fail to make this type of due diligence a part of their grant-making process. The due diligence task for technology development is undoubtedly complex and requires substantial resources, but there is great value in high-quality IP analysis. Integrating IP analysis with technical information permits decisions to be made based on the evidence and reduces risk.

Stage 3: Technology-specific IP management strategy

The insight gained and information generated through IP due diligence is used for creating a Disease Intellectual Property Plan (DIPP). The DIPP is used to advise GALVmed staff and to address questions from external parties, such as stakeholders, regarding GALVmed's intended IP management strategy for a specific disease-control technology. Aside from presenting the results of the IP due diligence process, DIPPs map the flow of technology from providers to development partners, manufacturers, and so on. This map allows GALVmed to identify the contractual arrangements needed for effectively governing IP transactions between the actors involved in a way that supports pro-poor sustainable delivery of technology. Moreover, by building upon the results of the due diligence process, GALVmed can make informed decisions on critical issues such as ownership and rights allocations as they relate to background and foreground IP.

Issues of ownership and rights allocation are often not straightforward where nonprofit organizations are engaged in technology development. There is, first, the question of whether the coordinating organization should own IP itself. Some would say there is an inherent discord between owning IP and being an "honest broker" that coordinates incentives among partners. However, the ownership of IP allows a facilitator organization to have more leverage in pushing for pro-poor outcomes. GALVmed does not seek to own IP, but it does not rule out the possibility of a future instance in which claiming ownership to IP rights could be critical to achieving the development and deployment of products for the poor.

Stage 4: Contracting

The strategy articulated in a DIPP is ultimately implemented through a set of contracts among partner organizations. Contract drafting and negotiations are among the most challenging and resource-consuming activities that GALVmed undertakes. Some contracts govern straightforward IP transactions. Under other circumstances, contracts need to capture more sophisticated strategies that deal with,

for example, issues of pro-poor performance obligations, geographical exclusivities, and activities for which a high degree of uncertainty exists. GALVmed's position as a facilitator in the RD&D process further complicates what might otherwise be a simple contract. As a facilitator, GALVmed engages multiple parties, often playing the role of an intermediary or broker (see module 3, TN 4, for a discussion of innovation brokers). GALVmed must structure contracts to ensure that there is a potential for leveraging to meet pro-poor goals, certain obligations from technology providers are integrated, and an effective recourse process is in place (should obligations be broken) with minimal impact on goals and milestones. In addition, GALVmed must ensure that the expectations of the technology provider and sublicensee are in compliance with one another. It is in GALVmed's interest to release market-ready products as soon as possible. Therefore it becomes GALVmed's responsibility to manage challenging negotiations with all involved parties in a timely and efficient way.

BENEFITS, IMPACT, AND EXPERIENCE

As this profile has illustrated, *IP management processes in the private sector are highly relevant to nonprofits* working to develop technology for the poor. IP management in the private sector minimizes risks and contributes key components to a commercialization strategy that supports the organization's goals. GALVmed, through its systematic approach to IP management, is better able to circumvent and/or minimize IP risks that could adversely affect downstream development and deployment operations (see the sections on IP landscaping and IP due diligence) and can use IP management to support its organizational goals. In the wider scheme of things, GALVmed's IP management system has benefited the organization pro-poor mission by addressing some broader issues that often delayed milestone deliverables, namely, the growth of innovation to sustainable, market-ready products.

One main point highlighted through GALVmed's experience in strategic IP management is that organizational missions and related policies, including IP policies, must be aligned with the ambitions of partners engaged in the RD&D process. Ultimately, the availability of GALVmed's products should not depend on the existence of GALVmed itself. For innovations to become meaningful products with wide adoption, partners, preferably private, must be incentivized to support the existence and availability of a product, throughout and beyond the existence of GALVmed. While GALVmed's facilitation in the development of a vaccine is purely humanitarian, private partners, who are crucial in ensuring that a technology becomes a successful product, are likely to have different ambitions, which must also be considered.

The need to foster stronger public-private partnerships has taught GALVmed to leverage the organization's interests while providing its partners with the opportunity to achieve their own internal mission. This understanding has served GALVmed enormously well while dealing with contentious IP issues and creating conditions for relationships and products conducive to success.

Another benefit GALVmed has enjoyed from its approach to managing IP is the ability to rapidly produce, negotiate, and secure agreements with different partners. The development of core IP principles and more attractive conditions for engaging partners have allowed the organization to significantly increase the rate at which it can negotiate contracts.

LESSONS LEARNED AND ISSUES FOR WIDER APPLICATION

GALVmed's experience in IP management (including its interaction with public and private partners) provides many lessons. A *key lesson* is that superficial surveys of IP are insufficient. All organizations working in the knowledge economy, in the public sector or otherwise, need to proactively address IP matters. Systematic IP management will improve efficient progress, reduce risk, and support the organizational mission, ultimately creating greater impact on livelihoods of the very poor.

The resources needed to implement IP management require organizational decisions to develop certain capacities in-house and determine which elements should be outsourced. Some have suggested that basic understanding of IP and access to patent information (such as information in public patent databases) is sufficient for most public sector operations. As demonstrated here, however, IP issues require significant expertise in analysis and the ability to develop solutions tailored to each project's goals. Public patent data require interpretation, informed analysis, and then translation into a sound IP strategy that serves the organization and its development goals.

GALVmed has found that a hybrid approach to IP capacity building, in which IP expertise is available both in-house and externally, serves the organization best. Internal sources are in closer contact with staff overseeing the RD&D process and can better capture and communicate the organization's needs and wants. External expertise, on the other hand, is

impartial, can provide in-depth analysis, and can highlight issues the organization may fail to see internally. External expertise has given GALVmed high-quality analysis and access to top-tier attorneys.

One of the most challenging issues GALVmed has experienced is that of contracting. GALVmed's facilitation role entails the development of multiple contracts and often lengthy negotiations. GALVmed is working toward a new approach that employs significantly simplified contracts fit for multiple purposes. The intention is to decrease the time between drafting and signing contracts, while still effectively integrating the necessary rights and obligations. In addition to benefits for GALVmed, simplified legal contracts benefit developing country partners without good access to legal expertise.

GALVmed has learned that *building in-house capacity to manage IP is only half of the equation.* IP management plays an integral role in achieving a desired result; many related factors, such as business development strategies, go hand-in-hand with IP management practices. Regardless of the diligence GALVmed puts into managing IP, a sustainable endeavor ultimately relies on a partner's ability to interpret GALVmed's knowledge of IP issues and integrate that knowledge into a sound business model for downstream application.

In GALVmed's case, this challenge can prove difficult to meet. The majority of the organization's partners for downstream deployment are from the developing world, and many suffer capacity constraints (either in financial or other resources) or lack experience with IP, complex contracting, the creation of business plans, and other key business tools.

Consequently, GALVmed has recognized that *the second half of the equation for success in commercializing technologies for the poor is to build capacity in its downstream partners.* GALVmed now hires business consultants to work alongside partners to create business plans and strategies that take advantage of the IP knowledge GALVmed holds. In some instances, GALVmed assists its partners by taking the lead in drafting and negotiating complex agreements between partners. This intervention provides the partners with practical experience for dealing with IP issues, while providing GALVmed with the opportunity to impart its knowledge and experience in IP management for pro-poor purposes. *Capacity building on a project-specific basis has made related processes, such as contracting, simpler.* GALVmed can now engage with partners who have a clearer understanding of the needs, steps, risks, costs, and inputs required for a sustainable venture.

In conclusion, GALVmed provides an example of how nonprofits engaged in research, development, and deployment of technologies for the poor can benefit from systematic IP management. IP management plays a key role in reducing risks and improving the organization's capacity to deliver on its mission. Most nonprofits do not have sufficient in-house capacity, and this profile illustrates how the balance of outsourced services and internal capacity can change as an organization grows. Lastly, GALVmed's experience indicates the importance of integrating capacity building in IP management; even where a nonprofit is challenged itself in IP management capacity, there are opportunities to share knowledge and continue to foster improvements in a partner's IP management skills.